

Discovering Pharmacy Error: Must Reporting, Identifying, and Analyzing Pharmacy Dispensing Errors Create Liability for Pharmacists?

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Going to the pharmacist does not always lead to healing. As more Americans are steered toward prescription drugs, the number of those falling victim to pharmacy errors is increasing. Errors are inevitable, and various solutions have been proposed to reduce pharmacy errors. Patients' lawyers believe holding pharmacists accountable for their actions is the solution, while pharmacists, in an attempt to reduce errors and limit liability, are examining why mistakes occur. The law reflects both of these groups' views—it provides a forum for holding negligent individuals liable and offers some protection for investigations into pharmacy error.

As the law has refined its view of pharmacist-patient relationships and the issue of pharmacy error has been litigated more frequently, pharmacists have challenged the laws used to hold them accountable for their errors. Increased liability has persuaded some pharmacists to refrain from examining their mistakes because they fear that the information may be used against them in lawsuits. This note argues that this strategy of trying to avoid investigations out of a fear of liability is misplaced. The law provides some protection in the form of privileges and evidentiary bars to shield studies of errors from their use in lawsuits because courts and legislatures realize that these protections will enhance public safety and health. Only through investigating errors will pharmacists learn why mistakes occur and discover ways to reduce the number of errors that they make. The fear of liability should not stop pharmacists from developing safer drug-dispensing practices. After all, the only guaranteed way to avoid a lawsuit is to eliminate errors.

I. INTRODUCTION

Americans currently rate pharmacists as some of the most trustworthy professionals in the country,¹ yet the threats of death² or injury³ linger every time

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¹ See David W. Moore, *Firefighters Top Gallup's Honesty and Ethics List: Nurses and Members of Military Close Behind*, Gallup News Service, at <http://www.gallup.com/poll/releases/pr011205.asp> (registration required) (Dec. 5, 2001) (revealing that pharmacists ranked fourth behind firefighters, nurses, and the military); Andrea

a pharmacist fills a prescription.⁴ One potential source of these injuries is the ethical and honest pharmacist.⁵ A variety of mishaps can occur behind the pharmacy counter, including: dispensing the wrong drug, giving the wrong dosage, passing along another patient's prescription, counting the wrong quantity, dispensing an expired drug, or typing the wrong instructions on a prescription bottle label.⁶ While death and serious bodily injury are the worst-case scenarios, pharmacy errors, even the worst ones, can paradoxically serve a positive purpose—they can help explain why these errors occur and how to minimize them in the future.⁷

Rock, *Prescription for Trouble: What Could Go Wrong at Your Pharmacy?*, MONEY, Apr. 1998, at 114, 117 (citing Gallup polls that have rated pharmacists as more trustworthy than pastors).

² See WALT BOGDANICH, THE GREAT WHITE LIE: DISHONESTY, WASTE, AND INCOMPETENCE IN THE MEDICAL COMMUNITY 70–80 (1991) (describing the deaths of two heart transplant patients arising from a hospital pharmacy dispensing the incorrect intravenous solution); see also James Lindemann Nelson, *Rush from Judgment*, in MARGIN OF ERROR: THE ETHICS OF MISTAKES IN THE PRACTICE OF MEDICINE 153, 153 (Susan B. Rubin & Laurie Zoloth eds., 2000) [hereinafter MARGIN OF ERROR] (noting that the number of patients killed “‘because of missed diagnoses, medication mishaps and other preventable errors’” is the equivalent of “[t]hree jumbo jets crashing every two days”) (quoting Michael M. Weinstein, *Checking Medicine's Vital Signs*, N.Y. TIMES, Apr. 19, 1998, § 6 (Magazine), at 36).

³ See, e.g., *McClure v. Walgreen Co.*, 613 N.W.2d 225, 229 (Iowa 2000) (relating facts in which a pharmacy error led to dizziness, falls, and fractured bones in a patient); Raja Mishra, *Error on Drug for HIV Alleged Dosage Mistake Let Virus Grow, Suit Says*, BOSTON GLOBE, December 26, 2001, at B1 (reporting on a civil suit seeking \$257,000 in damages that claimed a pharmacist's misfill led an HIV patient to develop an immunity to AIDS drugs).

⁴ Nearly half of all Americans took a prescription drug in 1999, spending an estimated \$100 billion. GEN. ACCOUNTING OFFICE, ADVERSE DRUG EVENTS: THE MAGNITUDE OF HEALTH RISK IS UNCERTAIN BECAUSE OF LIMITED INCIDENCE DATA, GAO/HEHS-00-21, 3 (Jan. 2000) [hereinafter GAO REPORT].

⁵ While pharmacists are well respected, surveys indicate that the public fears medical error. In a survey conducted by the American Society of Health-System Pharmacists, 61% of Americans were “very concerned” about receiving the wrong prescription and 58% about obtaining a drug that would negatively interact with another drug. AGENCY FOR HEALTHCARE RESEARCH & QUALITY, U.S. DEP'T OF HEALTH & HUMAN SERVS., AHRQ PUB. NO. 00-P037, MEDICAL ERRORS: THE SCOPE OF THE PROBLEM: AN EPIDEMIC OF ERRORS, <http://www.ahrq.gov/qual/errback.htm> (current as of Feb. 2000). The public's fear is not baseless because medical errors, which include dispensing errors, are seen as “a major source of iatrogenesis—disease or illness induced by medical treatment or diagnosis.” BARRY R. FURROW ET AL., THE LAW OF HEALTH CARE ORGANIZATION AND FINANCE 29 (4th ed. 2001).

⁶ *Error Terror*, CHEMIST & DRUGGIST (U.K.), Feb. 15, 1997, at SI, <http://www.LEXIS.com>, News Group File, All (relating causes of pharmacy errors).

⁷ See INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 87 (Linda T. Kohn et al. eds., 2000) (stating that the goal of reporting is to “remedy vulnerabilities in systems”).

These pharmacy mistakes are “complex sorrows,”⁸ because they involve the interaction of so many thoughts, concepts, people, and emotions. Some of the most trusted professionals with whom many patients place “blind faith”⁹ are injuring unsuspecting patients who believe the pill that they are ingesting will return them to health, not spiral them into greater and graver illness. Among the individuals affected by these errors are patients and their families, pharmacists, and doctors. The patients and their families must deal with the consequences of the error, the doctors must treat their patients for another ailment, and pharmacists must ponder what went wrong and why. Such a mistake becomes further complicated when patients want compensation for the harm done to them, folding lawyers and the law into this mix of complex sorrows.¹⁰ Not only has the patient’s medical condition become complicated, but the pharmacist’s troubles deepen as well. Reprimand from the employer and sanctions from boards of pharmacy are only the start of the pharmacist’s difficulties. They now face the lawsuit of an injured patient.¹¹

⁸ MARIANNE A. PAGET, *THE UNITY OF MISTAKES: A PHENOMENOLOGICAL INTERPRETATION OF MEDICAL WORK* 97 (1988). Though I borrow Paget’s terminology, I am not using the phrase in the same sense as she. Whereas Paget uses this phrase to describe “intellectualizations of action” (i.e., the process that the error-maker undertakes to discern why the error was made), I use this term to describe the multifaceted consequences of a pharmacy error. *Id.*

⁹ Rock, *supra* note 1, at 114, 117. Some argue that blind faith in any professional is foolish because “expertise and error lie at the heart of the professions.” PAGET, *supra* note 8, at 23 (quoting Donald Light, *Psychiatry and Suicide: The Management of a Mistake*, 77 AM. J. SOC. 821, 821–38 (1972)).

¹⁰ Two goals of the tort system are: (1) “to deter errors and maximize safety” and (2) “to provide compensation for those wrongfully injured.” BRYAN A. LIANG, *LEGAL IMPEDIMENTS TO PATIENT SAFETY: CHANGING THE SYSTEM TO REWARD DOING THE RIGHT THING* 26 (2000) (citation omitted). However, Liang argues that lawsuits for medical errors have not furthered these tort goals because error remains a problem and safety has yet to be maximized. *Id. But see* INST. OF MED., *supra* note 7, at 110 (stating that some believe holding people accountable will ensure that errors will not occur again). Another view is that error will always be tied to the tort system because medicine is “embedded in the larger moral system of our political and economic culture.” Since the culture defines negligence, it is the culture that will define error. John D. Lantos & Martha Montello, *Mistakes in Context*, in *MARGIN OF ERROR*, *supra* note 2, at 73, 74–75. This theory that culture shapes people’s conceptions then suggests that the means of keeping pharmacy errors out of litigation is to remove medicine from this larger culture that is interested in imposing a tort. *See id.*

¹¹ While this note deals specifically with civil litigation, cases do exist in which a pharmacist has been criminally charged with a dispensing error. In Toledo, Ohio, the Lucas County prosecutor’s office brought a charge of involuntary manslaughter against a pharmacist who dispensed the wrong drug dosage, quadrupling the amount that the patient should have received. The prosecutor pursued this criminal charge even after the state pharmacy board fined the pharmacist \$1500. *See Hospital Pharmacist Indicted in Death of a Cancer Patient*, BLADE (Toledo), Oct. 11, 2001, <http://www.toledoblade.com>, The Blade Archives. This case indicates

Once the legal element enters the arena, the law does not simplify the sorrow; instead, it adds to the complexity as the pharmacist and the patient become adversaries and as competing policy interests duel. In litigation, the patients, as plaintiffs, want as much information as possible about the pharmacists, using discovery to gather this information.¹² In contrast, the pharmacists want to limit their liabilities.

To minimize the frequency with which pharmacists and patients confront the complex sorrow and avoid the complexities of pharmacy mistakes, pharmacists have investigated ways to identify and reduce errors.¹³ The pharmaceutical industry and state pharmacy boards have studied these accidents through peer review and reporting systems.¹⁴ Also, these organizations have allocated resources to examine how often these errors occur, why they occur, and how to reduce them.¹⁵ Based on these investigations, pharmacists have implemented

that the prosecutor believed that reckless errors should not be excused merely because risk is associated with medicine.

¹² See generally 4 BENDER'S FORMS OF DISCOVERY: CORPORATIONS TO DRUGS & DRUGGISTS 548-58 (1963, updated through Supp. 1988) (suggesting plaintiffs' attorneys explore the following topics when conducting discovery into pharmacy error: (1) pharmacist qualifications such as degrees and pharmacy schools; (2) revocation of a license, if any; (3) the store record of prescriptions; (4) the type of prescription; (5) volume of prescriptions at the store; (6) safeguards in procedures; (7) past filling prescription mistakes; and (8) a description of the mistake).

¹³ See James T. Reason, *The Human Factor in Medical Accidents*, in MEDICAL ACCIDENTS 1, 12-15 (Charles Vincent et al. eds., 1993) (listing solutions that recognize the universality of human fallibility and that focus on the organization, not the individual); Carol Ukens, *Breaking the Trust: Exclusive Survey of Dispensing Errors*, DRUG TOPICS, Nov. 23, 1992, at 58, 69 (suggesting the following activities to reduce errors: counseling, inquiring into a patient's drug history, implementing procedures that ensure an individual is given the correct prescription, educating patients, calling the doctor to clarify, and analyzing the errors that occur); Tony Grasha, *A Cognitive Systems Perspective on Human Performance in the Pharmacy* 10 (June 21, 2000) (unpublished executive summary research report for National Association of Chain Drug Stores Education Foundation) (on file with the author) (reporting that self-monitoring reduced process errors by 21.7% in field sites); *Maybe Santa's on to Something . . . He Checks His List Twice, Shouldn't We?*, ISMP MEDICATION SAFETY ALERT, at <http://www.ismp.org/MSAarticles/Santa.html> (Dec. 12, 2001) [hereinafter *Maybe Santa's on to Something*] (stating that double checks of work are important in reducing errors); see also *infra* Part III (discussing the various means to identify and reduce errors).

¹⁴ See *Mandatory Reporting Programs: Why We Can't "Look the Other Way,"* ISMP MEDICATION SAFETY ALERT, at <http://www.ismp.org/msaarticles/mandatory.html> (May 31, 2000) [hereinafter *Mandatory Reporting Programs*] (stating that "reporting is fundamental to all error reduction efforts").

¹⁵ See, e.g., Grasha, *supra* note 13, at 10 (analyzing results of research on pharmacy errors). Not only does private industry fund research, but also the federal government has been involved. In 2001, the Agency for Health Care Research and Quality ("AHRQ") spent over \$43 million on ninety-four research grants aimed at studying how to reduce medical errors. See AGENCY FOR HEALTHCARE RESEARCH & QUALITY, U.S. DEP'T OF HEALTH & HUMAN SERVS.,

various improvements in pharmacy layouts and dispensing systems to further attempt to diminish error rates.¹⁶ Finally, pharmacists have been called on to perform self-monitoring, so that they can understand and discover why they make certain errors.¹⁷ Through all these methods of monitoring and examination, pharmacists, their employers, their professional boards, and other interested parties hope to understand the error-making process and any events surrounding an error, so that patient health can be improved in the future.

Though pharmacists have all these ideas and methods available to reduce errors, they are reluctant to use them because they fear the research and investigation will be open to legal discovery and evidentiary admissibility. If a jury learns of the results of prior investigations, which will reveal mistakes, pharmacists fear that this knowledge will assist injured patients in making a better case for negligence and may lead to larger compensatory damage awards and even punitive damages.¹⁸ Therefore, pharmacists have no interest in having all potentially relevant information placed into discovery or admitted into evidence. If such information is not immune from discovery or inadmissible at trial, the incentive to study systematically how to reduce errors will not exist, hindering the policy of promoting health.¹⁹ A choice, the pharmacists' interests claim, must be made—halt these activities aimed at reducing errors or keep this important information shielded from discovery.²⁰ The complex sorrow of the pharmacy error thus creates a tension between two valid but opposing positions. Either allow for those harmed by negligence to be fully compensated by collecting all relevant information for their claim, or permit these studies to be completely

AHRQ PUB. NO. 02-P006, FACT SHEET: PATIENT SAFETY RESEARCH INITIATIVES: FISCAL YEAR 2001, <http://www.ahrq.gov/qual/ps2001.htm> (current as of Nov. 2001).

¹⁶ Michael R. Cohen, *Preventing Dispensing Errors*, in MEDICATION ERRORS 9.1, 9.3–9.4 (Michael R. Cohen ed., 1999) (arguing that adequate space, distinct work areas, and highlighting commonly confused medications are ways to improve work environments); see also *McClure v. Walgreen Co.*, 613 N.W.2d 225, 236 (Iowa 2000) (citing an agreement between the defendant pharmacy and the Iowa Board of Pharmacy Examiners that would address work space problems).

¹⁷ See Grasha, *supra* note 13, at 10–17 (noting that self-monitoring raises awareness of mistakes and provides a learning experience); see also Ukens, *supra* note 13, at 58 (suggesting that one way to reduce error is to analyze those that do occur to see if a pattern exists).

¹⁸ See *McClure*, 613 N.W.2d at 234 (upholding a trial court's decision to allow pharmacy dispensing error reports into evidence, which contributed to a jury awarding punitive damages); *Harco Drugs, Inc. v. Holloway*, 669 So. 2d 878, 881 (Ala. 1995) (permitting the introduction of 233 pharmacy reports on errors into evidence, resulting in a jury's decision to award punitive damages).

¹⁹ See INST. OF MED., *supra* note 7, at 10 (arguing that discovery “undercut[s]” efforts to “detect and analyze errors to improve safety”).

²⁰ See *Mandatory Reporting Programs*, *supra* note 14 (citing a “major barrier to reporting is the potential loss of legal protection for the insightful analysis contained in reports”).

confidential, improving patient care and safety.²¹ What was once a seemingly routine matter of getting one's prescription filled has become a complicated legal battle where adversaries and competing public interests clash.

This note will focus on the complex sorrow that revolves around pharmacists and the law, and it will suggest that part of the solution for protecting pharmacists' attempts to reduce error lies in this complex law without sacrificing the interests that are important to the patient. Instead of immediately undertaking the difficult and slow-moving process of changing the law, pharmacists should realize that the present law currently provides some protection to shield information on pharmacy errors in the form of discovery immunities and evidentiary privileges. Outside of the law, pharmacists can take their own actions to protect themselves from error. If pharmacists concentrate on using the methods that they have directly under their control—reporting, peer review, and monitoring. These methods can provide a means of reducing liability. Instead of shunning these methods out of a fear of liability, pharmacists must realize that reducing errors is the only guaranteed way to avoid liability. Presently, the law allows for the injured to be compensated and the negligent to be held accountable, but this situation should not mean that patient care suffers or that efforts to reduce errors are inhibited because of a fear of liability.

Before this note proposes solutions, a few preliminary matters and background information will be reviewed. Part II of this note discusses the data on dispensing errors and the two predominant theories on why errors occur, while Part III discusses the various methods to identify and reduce errors and their perceived legal implications for liability. Part IV explains that pharmacists are becoming acutely aware of liability because of changes in the pharmacists' training and job duties.

With the conclusion of these background sections, the remainder of the note will discuss protections that the law provides and pose suggestions to help ease fears of liability. Part V briefly highlights the tension between the injured patient and pharmacist's positions from the perspective of the Federal Rules of Civil Procedure. In Part VI, this note explains the role of privilege in this conflict between pharmacists and patients and the privileges available to pharmacists, while Part VII highlights the role of evidence law in this conflict. Part VIII suggests why the law, as it stands, should not be an excuse for delaying the implementation of error reduction systems merely because the threat of liability may loom. Finally, Part IX provides a conclusion for this note.

²¹ See INST. OF MED., *supra* note 7, at 110 (reporting two conflicting views regarding whether pharmacy errors should be protected: (1) open access of litigation will "interfere[] with disclosure of errors"; and (2) "the public has a right" to know because liability leads to accountability). Proponents of shielding pharmacists' identities favor a mixture of practical protections like the promise of confidentiality and anonymous reporting, legal protections such as peer review and self-critical analysis privileges, specific legislation, and rules of privilege to provide full protection for pharmacists who report errors. *Id.* at 117–27.

II. PHARMACY DISPENSING ERROR BACKGROUND

A. *The Data on Pharmacy Errors*

In 1998, pharmacists filled nearly 2.5 billion pharmacy prescriptions at an estimated cost of \$92 billion;²² within hospitals, over 3.75 billion drugs were administered.²³ Since prescription drugs are used in such large quantities, the potential for error is great,²⁴ and the research suggests that with increasing prescription drug usage comes an increase in the number of injuries from medication errors.²⁵ Studies show that between 3% and 5% of prescriptions filled contain errors with .87% to 1.5% of these misfills being "potentially injurious to the patient."²⁶ These data indicate that pharmacists do make errors in dispensing drugs²⁷ and therefore play a significant role in patients' health and safety.²⁸ With the increasing chance and occurrence of serious injuries, lawsuits have followed.²⁹

²² *Id.* at 27 (citation omitted).

²³ *Id.* at 32 (citation omitted).

²⁴ See GAO REPORT, *supra* note 4, at 6 (citation omitted) (stating that "because so many drug doses are given, an estimated quarter to half of all [adverse drug events] among hospital patients result from medication errors").

²⁵ Medication errors have been described as "one of the most common types of error." INST. OF MED., *supra* note 7, at 28. A study of deaths attributed to pharmaceuticals found a two-and-a-half fold increase in deaths from medication errors between 1983 and 1993, which included administering mistakes, errors committed by medical personnel, and dispensing errors. *Id.* at 32. Besides affecting the patient, drug errors also have an economic impact. For example, by prolonging the length of hospital stays, these errors contribute to an additional \$2600 in costs to hospitals per adverse drug event. BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS, AND PROBLEMS 35 (3d ed. 1997) (citing David W. Bates et al., *The Costs of Adverse Drug Events in Hospitalized Patients*, 277 JAMA 307, 307 (1997)).

²⁶ See Anthony F. Grasha & Michael O'Neil, *Cognitive Processes in Medication Errors*, U.S. PHARMACIST, June 1996, at 96, 101 (summarizing studies on pharmacy errors).

²⁷ The Pharmacists Mutual Insurance Company states that 85% of its claims are a result of "mechanical errors," such as dispensing the wrong drug or dose, or making label errors. Walter L. Fitzgerald & Dennis B. Wilson, *Medication Errors: Lessons in Law*, DRUG TOPICS, Jan. 19, 1998, at 84, 86.

²⁸ One study of dispensing errors in California and Oregon pharmacies found that each pharmacy made an average of 324 dispensing errors per year. Rock, *supra* note 1, at 114, 115.

²⁹ See generally Fitzgerald & Wilson, *supra* note 27, at 84, 86 (discussing the "rising" liability claims against pharmacists and citing the following reasons for liability claims: (1) incorrect drug dispensed; (2) wrong dosage; (3) incorrect directions; and (4) failure to detect prescribing error).

B. *The Theory of Error*

Those who research errors view with chagrin the truism that an error will lead to a lawsuit, believing that the advancement of knowledge should not be hindered by calculations of fault, damages, and probable liability.³⁰ Researchers prefer to state their hypotheses, findings, and recommendations without worrying about who will be sued as a result.³¹ The following briefly describes some of the theory behind error and in particular why pharmacists can never operate error-free, at least not under the present conditions.³²

Humans, by their nature, have a “propensity for committing errors”;³³ we are fallible. However, this does not mean that human activity is dominated by errors or that the number of errors cannot be reduced.³⁴ Though human error is inevitable, it is rare when compared with the frequency with which tasks are performed error-free.³⁵ The study of error is driven by the axiom that errors are

³⁰ Reason, *supra* note 13, at 12 (stating that “such a ‘blame culture’ [i.e., a litigious outlook in a society where people are looking for someone to sue] is of little or no use in understanding the complex interaction between various causes of medical mishaps or in identifying the appropriate remedial measures”); cf. GEORGE J. ANNAS, *STANDARD OF CARE: THE LAW OF AMERICAN BIOETHICS* 4 (1993) (warning that health care providers “are taking the law too seriously—and are in danger of letting fear of liability replace reasoned judgment, and abdicating their responsibility to define ‘good medical care’ and set the standard for such care”). Annas also argues that “defensive medicine” (i.e., acting to prevent lawsuits instead of to treat the patient in the best capacity), while legal, is “by definition unethical.” *Id.*

³¹ Reason, *supra* note 13, at 12; see J.W. Senders, *Medical Devices, Medical Errors, and Medical Accidents*, in *HUMAN ERROR IN MEDICINE* 159, 170 (Marilyn Sue Bogner ed., 1994) (arguing that the frequency of litigation makes risk managers, insurance specialists, and legal counselors the exclusive parties involved in analyzing errors, which is problematic because these professions are not “qualified to study error”).

³² Some have suggested that the culture of medicine hinders the discussion of errors, isolating those who commit them, thus making error reduction difficult. When errors are detected, the medical system, using the “perfectibility model” (a paradigm theory in which the norm in medicine is mistake-free action), blames the individual, and therefore focuses on the individual to find solutions. See FURROW ET AL., *supra* note 5, at 44–46 (reprinting an excerpt from Lucian L. Leape, *Error in Medicine*, 272 *JAMA* 1851 (1994)). Instead of clinging to the perfectibility model, others have suggested that the medical field should survey other professions and industries’ attempts to reduce errors. The aviation model has been offered as one example of having achieved great success in curtailing airline mishaps. By recognizing the inevitability of error, the aviation model creates a system where there is standardization of procedures, rigorous training, examination, and certification systems, and effective regulation of the aviation industry. FURROW ET AL., *supra* note 25, at 43.

³³ Reason, *supra* note 13, at 3.

³⁴ *Id.*

³⁵ JAMES REASON, *HUMAN ERROR* 2 (1999); see also Charles Vincent, *The Study of Errors and Accidents in Medicine*, in *MEDICAL ACCIDENTS*, *supra* note 13, at 18 (noting that not only are errors rare, but that the proportion of accidents involving negligence is very small).

predictable and that the only way to predict errors is to examine the factors that cause them.³⁶ Three universal elements of mistake have been identified: (1) all humans make “fallible decisions and commit unsafe acts;” (2) all man-made systems contain error; and (3) all human activity has some risk.³⁷

Given these assumptions, pharmacy error will never be completely excised; however, researchers have endeavored to explain why pharmacy errors occur and to suggest ways to reduce errors.³⁸ Two theories propound the reason for errors: (1) the systems (or organizational) perspective;³⁹ and (2) the cognitive perspective.⁴⁰ Though each theory has different views on what ultimately causes error,⁴¹ both have tailored solutions to reach a common goal—to identify and remove the source of errors.⁴²

³⁶ Reason, *supra* note 13, at 3.

³⁷ *Id.* at 3.

³⁸ The following reasons have been listed as causes of dispensing errors: (1) heavy work load; (2) patient pressure (i.e., statements encouraging speed because “ice cream is melting, . . . live chickens [are] in the trunk, or . . . an appointment” awaits); (3) similar packaging; (4) failure to check the drug before it is dispensed; (5) illegible physician script; and (6) look-alike or sound-alike prescription drugs. Ukens, *supra* note 13, at 60–61.

³⁹ Reason, *supra* note 13, at 12. The systems theory suggests that the focus should shift away from the individual and toward the entire system as the reason for the existence of an error. Therefore, if the component of the system responsible for the error (“the latent failure” or “resident pathogen”) is found and corrected, the error will no longer occur. *Id.* at 13. However, proponents of the theory warn that a “faulty” design in the system will remain hidden until an individual operating in the system makes an error, exposing the system’s flaw. *Id.* Examples of systems flaws include poor training of personnel and incorrect work schedules. See Lucian L. Leape, *A Systems Analysis Approach to Medical Error*, in MEDICATION ERRORS, *supra* note 16, at 2.1, 2.5–2.6. Therefore, a pharmacist who commits an error by dispensing a sound-alike drug would not be deemed at fault under the systems perspective. Instead, the system would be to blame for not emphasizing the problems associated with sound-alike drugs or for not providing sufficient training on this topic.

⁴⁰ Grasha, *supra* note 13, at 3. This cognitive perspective hypothesizes that errors occur because a variety of psychosocial factors—interpersonal problems, perceptions of workload, personality characteristics, and sleep deprivation—contribute to pharmacist error by interfering with mental functioning. Anthony F. Grasha, *Misconceptions About Pharmacy Workload*, CAN. PHARM. J., Apr. 2001, at 26, 35. This psychosocial approach uses a cognitive model that recognizes two primary modes of mental functioning—automatic thinking, in which no effort is put into the activity, and problem solving. Errors occur during both thought processes. In automatic mode, an error, known as a slip, occurs because of some distraction at a critical moment, such as fatigue. In contrast, an error occurs in a problem-solving mode when an individual has made some rule-based mistake such as overgeneralization. (Humans recognize certain patterns, which trigger a certain sequence of thought processes; however, if a pattern is incorrectly identified, the wrong thought processes will be triggered, causing an error.) Leape, *supra* note 39, at 2.3–2.4.

⁴¹ These two perspectives are not entirely compatible because theorists from both camps often find the other outlook to be ineffective. See Leape, *supra* note 39, at 2.5 (arguing a

III. THE COMPLEXITY OF REDUCING PHARMACY ERRORS

Out of this research on error and through traditional quality assurance and risk management principles⁴³ have come a number of suggestions for identifying errors that in turn have resulted in suggestions for reducing errors.⁴⁴ Some of the most popular include: peer review, critical self-evaluation, reporting, incident reports, changes in pharmacy layout and procedures, and altering relationships between pharmacists, doctors, and patients. While these methods of reducing errors exist, not all of them have been fully implemented because pharmacists and their employers fear the complexities that will result, including exposure to further liability.⁴⁵ For instance, pharmacists believe that documentation or records of pharmacists' errors and examples of improvements in the pharmaceutical field might enhance a case of negligence.⁴⁶ The following discusses some of these error-reducing methods and reasons that pharmacists fear them.

A. Peer Review

Peer review is a means of reviewing errors through a closed, confidential meeting presided over by one's professional peers for the purpose of improving patient care.⁴⁷ These peer reviews can be organized by an employer, initiated by a

weakness of the psychological and human factors research is its failure to develop a means of preventing errors).

⁴² See Reason, *supra* note 13, at 13–14 (suggesting that solutions be aimed toward designing systems that recognize humans' propensities to err and making system design problems "more transparent").

⁴³ There is a distinction between quality assurance and risk management. Risk management gathers data to find problem areas in an operation, which incidentally help to prevent errors, so that it can reduce the causes and effects of loss on an organization. Quality assurance differs in that it focuses on assessing and improving patient care. BARRY R. FURROW ET AL., *HEALTH LAW* 128–29 (2d ed. 2000).

⁴⁴ Common causes of pharmacy dispensing errors that are addressed by these measures include: (1) use of outdated and incorrect references; (2) failed communication like a doctor's illegible handwriting; (3) look-alike and sound-alike drugs; (4) poor drug distribution practices; (5) dose miscalculations; (6) problems in labeling and packaging; (7) distribution of a prescription to the wrong person; and (8) poor patient education. Michael R. Cohen, *Causes of Medication Errors*, in *MEDICATION ERRORS*, *supra* note 16, at 1.1, 1.2–1.7.

⁴⁵ See INST. OF MED., *supra* note 7, at 109 (stating that "[t]he potential for litigation may sometimes significantly influence the behavior of physicians and other health care providers").

⁴⁶ *Id.* at 112–13 (reporting that information gathered by peer review committees, risk managers, and others helps plaintiff's counsel to build a case because this information can be used to prove causation).

⁴⁷ See Robert W. McCann, *Protection and Disclosure of Medical Peer Review Information*, in 1989 *HEALTH LAW HANDBOOK* 423, 423 (Alice G. Gosfield ed., 1989) (defining peer review as "any review of professional medical activity"); see also *Brem v. DeCarlo*, 162 F.R.D. 94, 97 (D. Md. 1995) (stating that the Maryland legislature codified a peer

professional society, or created through some other means. Usually, proceedings are immune from discovery, but states vary regarding their norms and criteria.⁴⁸ Since there is neither Congressional legislation recognizing a peer review privilege⁴⁹ nor consistent federal court precedent dealing with this subject,⁵⁰ pharmacists must rely on state statutes to provide protection, many of which may be drafted in such a way as to fail to provide full protection.⁵¹

Those states that do offer this peer review privilege⁵² might have loopholes and gaps that permit the admission of some peer review information. For example, most statutes do not provide protection if information is shared among peer review panels from different states.⁵³ Without federal protection, pharmacists must rely on state privilege. There are two implications for pharmacists. First, this means that they are left to rely on the protection of a potentially ineffective or limited statute.⁵⁴ Second, if a case is brought before a federal court, even if it is exercising pendent jurisdiction, the court will generally follow federal law and the federal rules of discovery and evidence, which do not look favorably upon a peer review privilege.⁵⁵ Without peer review protection in the federal arena, a plaintiff would have access to peer review information from suits filed in federal court. Hence peer review, while protected in certain states,⁵⁶ has little protection in the federal system.

review privilege "to foster effective review of medical care and thereby improve the quality of health care").

⁴⁸ However, two common goals have been gleaned from a perusal of peer review statutes: (1) to make the process confidential; and (2) to protect participants from civil liability claims. FURROW ET AL., *supra* note 43, at 132.

⁴⁹ See *infra* notes 134–39 and accompanying text.

⁵⁰ See *infra* notes 201–04 and accompanying text.

⁵¹ McCann, *supra* note 47, at 428, 431 (stating that peer review statutes will only protect groups explicitly mentioned in the statutes and that these statutes solely cover material, information and opinions developed through the peer review process).

⁵² See *infra* note 141 (listing some states that provide a peer review privilege).

⁵³ See INST. OF MED., *supra* note 7, at 120 (noting that the law does not protect information contained in error reports when the information is transmitted to out-of-state agencies).

⁵⁴ McCann, *supra* note 47, at 438 (observing that "most problems relating to the protection of peer review confidentiality arise from imprecision in the drafting of state confidentiality statutes").

⁵⁵ See *Tucker v. United States*, 143 F. Supp. 2d 619, 622–23, 627 (S.D. W. Va. 2001) (applying federal law in a case involving both federal and state law claims and refusing to recognize a federal peer review privilege); see also *infra* notes 198–206 (discussing the common law peer review privilege and its general lack of acceptance among jurisdictions). But see *Holland v. Muscatine Gen. Hosp.*, 971 F. Supp. 385, 389 (S.D. Iowa 1997) (noting that some weight can be given to state law and state public policy when considering privilege claims in federal courts).

⁵⁶ See *infra* note 141.

B. Risk Management

Risk management is the process of making and implementing decisions to minimize adverse effects of errors.⁵⁷ One method of reducing and identifying errors is incident reports,⁵⁸ which are factual summaries of errors that are generated after every instance of error. The problem with filing these reports, from the pharmacists' perspective, is that the incident reports are rarely protected from discovery.⁵⁹ Since these reports primarily deal with factual matters (who was injured, by whom, and for what reason),⁶⁰ their factual basis lends itself to being open to discovery. Without any protection, pharmacists would be reluctant to rely on these employer-initiated attempts to examine errors.⁶¹

C. Voluntary and Mandatory Reporting

While incident reports are one method of risk management, a system of reporting errors is viewed as the "cornerstone," i.e. "the heart" of risk management.⁶² Two general types of reporting systems exist—mandatory and voluntary reporting. Both have the same ultimate goal—to reduce errors by using pharmacist reports to study patterns of errors and reporting;⁶³ however, they diverge in the ways that they try to accomplish these goals. A voluntary system attempts to achieve its goal by creating a confidential system in which a pharmacist feels safe enough to reveal information because there is little likelihood that the pharmacist will be identified.⁶⁴ However, the mandatory

⁵⁷ Judy L. Smetzer et al., *The Role of Risk Management in Medication Error Prevention*, in MEDICATION ERRORS, *supra* note 16, at 19.1, 19.1.

⁵⁸ See FURROW ET AL., *supra* note 43, at 129 (stating that incident reports are the "most important tool" of risk managers).

⁵⁹ *Id.* at 132–33 (reporting that only a small number of states have enacted statutes protecting incident reports because they are (1) created by employers; (2) used for business purposes; and (3) viewed as the best source of information to explain a particular accident); *see also infra* notes 173–81 and accompanying text (discussing two cases in which incident reports led to punitive damages).

⁶⁰ See FURROW ET AL., *supra* note 43, at 129 (describing incident reports).

⁶¹ See generally *Harco Drugs, Inc. v. Holloway*, 669 So. 2d 878 (Ala. 1995) (upholding punitive damages in a case where incident reports helped to establish wanton behavior by the pharmacy); *McClure v. Walgreen Co.*, 613 N.W.2d 225 (Iowa 2000) (affirming a jury's award of punitive damages that was influenced by the admission of incident reports into evidence); *infra* notes 173–81 and accompanying text.

⁶² See Smetzer et al., *supra* note 57, at 19.2.

⁶³ See INST. OF MED., *supra* note 7, at 86–87.

⁶⁴ *Id.* at 87; *see also Patient Safety—What Is the Role of Congress: Hearing Before the Senate Comm. on Health, Educ., Labor, and Pensions*, 107th Cong. 57–58 (2001) [hereinafter *Patient Safety*] (testimony of James P. Bagian, M.D.) (comparing the success of the Aviation Safety Reporting System, in which 500,000 airline error reports have been handled without a

system is altogether different. Besides having the purpose of studying and reducing errors, mandatory systems also aim to hold individuals accountable by punishing those who make mistakes.⁶⁵ Since parties must report errors, their identities are known, making them open not only to punishment but also to liability.⁶⁶ By identifying those who make mistakes, the mandatory reporting system becomes valuable to litigants,⁶⁷ while at the same time hindering the ability to fully understand errors.⁶⁸ When a mandatory reporting body receives notice of errors, it will inevitably make a finding on some issue related to proving negligence (incompetence, fault, causation) when it punishes, providing a plaintiff not only information about the error but an independent assessment that might suggest liability.⁶⁹ As a result, pharmacists are reluctant to implement or agree to reporting systems, so long as they are open to discovery.⁷⁰

breach of confidentiality with that of New Zealand's aviation reporting system that failed because of breaches of confidentiality).

⁶⁵ See *Discussion Paper on Adverse Event and Error Reporting in Healthcare*, ISMP MEDICATION SAFETY ALERT, at <http://www.ismp.org/msaarticles/concept.html> (Jan. 24, 2000) (explaining one argument for disclosure of pharmacists' errors to be that reporting is part of an accountability system).

⁶⁶ See Smetzer et al., *supra* note 57, at 19.9. If pharmacists can avoid this mandatory reporting, they will. Underreporting will then create a "false sense of security" because it leads to fewer reports of errors, causing the public to presume incorrectly that fewer pharmacy errors exist. *Id.*

⁶⁷ *Mandatory Reporting Programs*, *supra* note 14.

⁶⁸ See *Patient Safety*, *supra* note 64, at 57–58 (testimony of Bagian, M.D.) (noting that "public safety suffers [if there is no confidentiality] because problems cannot be identified early and corrected"). While some might argue that this confidentiality hinders patient safety because it denies injured patients important information, advocates of confidentiality counter that reporting is separate from accountability systems. Confidentiality advocates argue that since methods of holding pharmacists accountable already exist, reporting systems do not diminish patient safety or pharmacist punishments; instead, confidential reporting provides new information to help study errors. *Id.* at 58; see also Smetzer et al., *supra* note 57, at 19.6–19.8 (noting a fear of liability inhibits reporting, leading to underreporting of errors).

⁶⁹ A pharmacist may always bypass this result by settling with the pharmacy board. Once the issue is settled, the possibility of any findings of fault by the pharmacy board is precluded. Also, whatever information is contained in the settlement agreement will not be admitted into evidence pursuant to Federal Rule 408 or its state law counterparts, which shield evidence of settlement negotiations and agreements from being admitted into evidence. See *State ex rel. Malan v. Huesemann*, 942 S.W.2d 424, 426–28 (Mo. Ct. App. 1997).

⁷⁰ See INST. OF MED., *supra* note 7, at 10 (arguing "a more conducive environment is needed to encourage health care professionals . . . to identify, analyze, and report errors without threat of litigation").

D. Research

Scholarly research on pharmacy errors examines a variety of theories of error in the pharmacy setting. Whether the studies focus on a systems perspective or a psychosocial view,⁷¹ important information on errors is being gathered that might be of interest to litigants. If a plaintiff were to obtain data that were used by a pharmacist to record or examine errors, the litigant might have some basis for establishing negligence. For instance, a pharmacist-participant in a study might report that ten errors occurred in the past week. While most of these errors may be caught at some later stage in the process, their occurrence might suggest liability to a jury if introduced in court. Therefore researchers must implement their own confidential protections⁷² or run the risk that their study will be open to discovery and will reveal who is making errors and why. Allowing discovery to expose this research hampers error reduction because pharmacists are reluctant to participate in valuable research.

E. Pharmacy Environment

Studies of the pharmacy environment have also revealed ways to reduce errors immediately. Some suggestions include allowing doctors to directly input a prescription into a computer database, focusing on drugs that are commonly involved in errors, giving unique sounding names and packaging to different drugs, and increasing the role of pharmacists in a patient's medication therapy.⁷³ These remedies, created to reduce the prevalence of pharmacy error, might come under legal scrutiny if a plaintiff decides that implementing a measure to prevent error is an admission of liability. While Federal Rule 407⁷⁴ denies the admission of remedial measures into evidence for the purpose of establishing negligence, this information can be admitted for other purposes, such as impeaching a

⁷¹ See *supra* notes 39–42 and accompanying text.

⁷² See Grasha, *supra* note 13, at 7 (creating a confidential design for a research study by using an anonymous mailing system to avoid learning pharmacists' identities).

⁷³ GAO REPORT, *supra* note 4, at tbl. 1. Other solutions to improving the pharmacy environment include: (1) workplace management through monitoring and careful selection of inventory, setting hours of operation so that a pharmacist is on duty when drugs are requested, and computer screening for allergies, drug contraindications, and dose limits; (2) independent checking procedures, which encompass keeping the order, prescription label, and medication together at all times; (3) work performance assessments by reviewing prescriptions for obvious errors and for potential look-alike or sound-alike drugs; and (4) patient counseling about the medication, side effects, and proper dosage (83% of errors are caught during this counseling). Cohen, *supra* note 16, at 9.2–9.18.

⁷⁴ See *infra* note 207.

witness.⁷⁵ Thus, these activities, while they might be beneficial in reducing errors, also might insinuate negligence or wrongdoing.

F. Self-Monitoring

A final method of reducing error is self-monitoring. Researchers suggest that monitoring one's errors can serve the useful function of highlighting to individual pharmacists why errors occur.⁷⁶ Perhaps these pharmacists will see a pattern in their errors or determine why errors occur at certain times. While these data are quite useful to the pharmacist, they could also be extremely valuable to the litigant who wanted to sue this pharmacist for negligence. Hence these self-evaluations, if kept on record, can provide a dual and dueling purpose—they serve a private purpose of educating and reducing errors, while also providing a possible public purpose of censure, blame, and negligence. Without some protection for this information, pharmacists are unlikely to maintain a record of this self-analysis,⁷⁷ which has proven helpful in reducing error in the research setting.⁷⁸

Without medical and medication errors, the medical and pharmaceutical fields would never have developed these six techniques of reducing errors. By serving a beneficial purpose, some have referred to these errors as “good errors.”⁷⁹ Labeling an error as *good* is not meant to praise one who has committed the error; instead, this term, recognizes that the only way to examine and discover solutions for errors is if they occur.⁸⁰ Pharmacists, however, are not quick to adopt this view of a beneficial, positive error. Over the past decade, the standard of care for pharmacists has been expanding, which increases the potential for liability.⁸¹ While pharmacists believe that it is important to discover why errors occur to reduce the number of errors and increase patient safety, they are reluctant to adopt these measures in light of the expanding standard of care for fear of

⁷⁵ See *infra* note 215 and accompanying text.

⁷⁶ See Grasha, *supra* note 13, at 9–10 (proposing that “[p]eriodic self-monitoring of process errors should become part of the quality assurance processes used in a pharmacy” because pharmacists’ review of their mistakes led to a reduction in errors by 21.7%).

⁷⁷ Cf. INST. OF MED., *supra* note 7, at 10, 109, 112 (noting repeatedly that fear of liability inhibits actions that potentially could lead to a reduction in errors).

⁷⁸ See Grasha, *supra* note 13, at 10 (reporting that self-monitoring reduced errors by as much as 21.7%).

⁷⁹ Theo Wehner & Michael Stadler, *The Cognitive Organisation of Human Errors: A Gestalt Theory Perspective*, 43 APPLIED PSYCHOL.: INT’L REV. 565, 570 (1994) (noting that an “erroneous action is a necessary prerequisite in the successful search for a solution” because an error is a means of problem solving).

⁸⁰ See *id.* (recognizing the “productivity of error assessment”).

⁸¹ See Walter L. Fitzgerald Jr., *Pharmaceutical Care and the Law*, DRUG TOPICS, Sept. 4, 1995, at 68.

repercussions.⁸² Therefore, they do not want to add legal complexity by adopting processes that could further increase their exposure to liability.

IV. THE COMPLEXITY BEHIND EXPANDING THE STANDARD OF CARE FOR PHARMACISTS

A. *The Traditional Practice Paradigm*⁸³ for Pharmacists

Pharmacists have always owed a duty⁸⁴ to patients.⁸⁵ However, the standard of care⁸⁶ that the pharmacist must exercise has evolved over time.⁸⁷ In general,

⁸² *Mandatory Reporting Programs*, *supra* note 14 (stating that the "major barrier to reporting is the potential loss of legal protection for the insightful analysis contained" in pharmacy error reporting).

⁸³ This phrase comes from Alison G. Myhra, *Pharmacist's Duty to Warn in Texas*, 18 REV. LITIG. 28, 33 (1999).

⁸⁴ Duty involves the question of whether one party has an obligation for the benefit of another. Therefore, the duty "is always the same—to conform to the legal standard of reasonable conduct in light of the apparent risk." *Dooley v. Everett*, 805 S.W.2d 380, 384 (Tenn. Ct. App. 1990) (quoting W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 53 (5th ed. 1984)). Once this duty is breached, negligence can only be found if the breach proximately causes damage. A patient proves negligence when there is: (1) irreversible damage; (2) a dereliction of the duty; and (3) a direct effect from specific acts. *PAGET*, *supra* note 8, at 133.

⁸⁵ See *Kohl v. Am. Home Prods. Corp.*, 78 F. Supp. 2d 885, 890 (W.D. Ark. 1999) (stating that a pharmacist's traditional duty was "that of technical accuracy in the filling of the prescription"); *Hooks SuperRx, Inc. v. McLaughlin*, 642 N.E.2d 514, 517 (Ind. 1994) (reasoning that since a direct relationship exists between a pharmacist and a customer, a duty arises between the two); see also Myhra, *supra* note 83, at 34–35 (stating that the traditional duty to patients was based on a standard of care that only encompassed the technical act of dispensing drugs).

⁸⁶ Standard of care is described as a term "denoting the level of conduct a . . . health care provider must meet in treating a patient so as not to be guilty of negligence." *ANNAS*, *supra* note 30, at 4. Its meaning in the health care context is "what a reasonably prudent physician (or specialist) would do in the same or similar circumstances." *Id.* By asking whether an activity will lead to liability, some argue that a pharmacist or other health care provider explicitly relinquishes to lawyers and judges the "responsib[ility] for setting the medical standard of care." *Id.* The standard of care is distinguished from a duty in that the standard of care describes the "scope of the duty." *Dooley*, 805 S.W.2d at 384.

⁸⁷ *Lasley v. Shrake's Country Club Pharmacy, Inc.*, 880 P.2d 1129, 1132 (Ariz. Ct. App. 1994) (distinguishing between a duty to a patient and the pharmacist's standard of care, which the court sees as expanding). The court in *Shrake* states that duty encompasses the relation between individuals to the extent that a legal obligation exists. On the other hand, standard of care involves particular conduct when a duty exists. Thus, if a duty is found, the court must look to see if the pharmacist conformed to the appropriate standard of care. *Id.* For example, in *Huggins v. Longs Drug Stores Cal., Inc.*, 862 P.2d 148 (Cal. 1993), the California Supreme Court found that a pharmacist owed no duty to the parents of an infant injured by a dispensing

pharmacists must exercise the care of pharmacists in the same or similar communities.⁸⁸ Therefore, changes in the pharmacy profession should be reflected in the standard of care owed to the patient. Traditionally, the law recognized pharmacists as drug dispensers.⁸⁹ Thus, liability arose only if the pharmacist supplied or processed the wrong drug.⁹⁰ Courts emphasized the technical aspects of the profession instead of the pharmacists' ability to counsel and warn of adverse drug interactions.⁹¹ To expand this standard of care, a plaintiff had to show by affidavit, expert opinion, legislative policy, or industry publications that the community practice was otherwise.⁹² However, with a long line of precedent suggesting that the pharmacist was only responsible for dispensing, courts rarely recognized an expanded standard of care.⁹³

Precedent was not the only factor working against plaintiffs who were suing pharmacists in courts operating under the traditional paradigm because courts also relied on other policies or doctrines to shield the pharmacist from liability. Under the "unavoidably unsafe" doctrine,⁹⁴ courts are reluctant to create liability for

error. *Id.* at 154. Without such a duty, the court was not required to examine whether the pharmacist met the standard of care required by pharmacists in the community; liability simply did not exist. *Id.*; see also ROBERT D. MILLER & REBECCA C. HUTTON, *PROBLEMS IN HEALTH CARE LAW* 395 (8th ed. 2000) (observing that the pharmacists' "standards of practice" come from federal and state legislation, agency regulations, ordinances, and court decisions).

⁸⁸ *Dooley*, 805 S.W.2d at 384–85 (stating that "[p]rofessionals are judged according to the standard of care required by their profession").

⁸⁹ *Kohl*, 78 F. Supp. 2d at 890; see also Myhra, *supra* note 83, at 39 (noting that "the common law imposes a legal duty on pharmacists to exercise the highest degree of care in filling prescriptions").

⁹⁰ See Myhra, *supra* note 83, at 40 (reporting cases in which liability was imposed for incorrectly filling a prescription).

⁹¹ *Id.* at 30, 34; see also R. Paul Asbury, Comment, *Pharmacist Liability: The Doors of Litigation are Opening*, 40 SANTA CLARA L. REV. 907, 910 (2000) (describing how the courts traditionally viewed pharmacists as being responsible for accurately filling prescriptions).

⁹² Fitzgerald, *supra* note 81, at 68, 69–71.

⁹³ See *Kohl*, 78 F. Supp. 2d at 890 (stating that it was only recently that courts began to move away from the traditional view); see also Myhra, *supra* note 83, at 46–56 (explaining that courts under the traditional paradigm have not extended the standard of care because of the learned intermediary doctrine and respect for the physician-patient relationship).

⁹⁴ The unavoidably unsafe doctrine states that a product with beneficial properties (e.g., a pharmaceutical drug with healing potential) that is properly prepared and accompanied by warnings and directions will not make a manufacturer or seller of the product liable. Therefore, "[t]he seller of such products . . . is not to be held to strict liability for unfortunate consequences attending (prescription drug) use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." See *Werner v. UpJohn Co., Inc.*, 628 F.2d 848, 858 (4th Cir. 1980) (quoting RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965)). Thus, under this doctrine, pharmacists are not liable because, although medications are dangerous substances, they also

those who dispense or manufacture "vital medications."⁹⁵ Also, courts have been concerned that imposing a requirement on pharmacists to discuss treatment and medications with a patient would interfere with the physician-patient relationship.⁹⁶ With this perspective, courts invoked the learned intermediary doctrine⁹⁷ because they viewed physicians, not pharmacists, to be in the best position to monitor and warn patients.⁹⁸

B. *The Contemporary Paradigm*⁹⁹

Since the 1990s, courts have begun to recognize a shift in the standard of care. Though the duty remains to the patient, the standard of care has expanded,

have healing potential. The benefit of providing medication is greater than the danger of harm. See Asbury, *supra* note 91, at 913.

⁹⁵ See Asbury, *supra* note 91, at 912-13.

⁹⁶ See Fitzgerald, *supra* note 81, at 68, 70; see also Kohl, 78 F. Supp. at 893 (following this traditional paradigm by holding that a pharmacist does not have "the duty to supply information about the risks of drugs that have already been prescribed" but does have the "duty to fill prescriptions as prescribed and properly label the prescriptions"); Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d 1129, 1133 (Ariz. Ct. App. 1994) (stating that some courts have been reluctant to impose a duty to warn because of fears that the pharmacists will "second guess" doctors' prescriptions).

⁹⁷ The learned intermediary doctrine usually is applied to the following three-party relationship: the drug manufacturer, the doctor, and the patient. When the manufacturer adequately informs the doctor of the dangers of the drug, the manufacturer no longer is liable because the doctor becomes the learned intermediary. Courts have analogized this situation to the doctor-pharmacist-patient relationship and found that no duty to warn exists for the pharmacist because the physician remains the learned intermediary. In an adverse side effect situation, the pharmacist would not be liable to the patient because the doctor presumably has information about the drug and about the patient's medical history. Therefore, the physician should have informed the patient of the potential adverse consequences, not the pharmacist. See Dooley v. Everett, 805 S.W.2d 380, 386 (Tenn. Ct. App. 1990) (stating that the learned intermediary doctrine "has recently taken a quantum leap" by shielding a pharmacist from the duty to warn just as it shields the manufacturer); Myhra, *supra* note 83, at 48-49 (citing cases in which the learned intermediary doctrine shielded pharmacists from liability because physicians knew the patient's history and had better training while pharmacists were unable to "weigh properly the risks and benefits of a proposed drug therapy or to ascertain what drug-related information the patient should receive"); David W. Hepplewhite, *A Traditional Legal Analysis of the Roles and Duties of Pharmacists*, 44 DRAKE L. REV. 519, 551 (1996) (noting that some courts have used the doctrine "on the basis that only physicians are learned intermediaries"). But see Myhra, *supra* note 83, at 48 (reporting that other states' courts have recognized pharmacists' duty to protect patients under the learned intermediary doctrine because pharmacists have the knowledge and are in the position of a learned intermediary).

⁹⁸ Asbury, *supra* note 91, at 912; see also Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383, 1385-86 (Pa. 1991).

⁹⁹ Myhra, *supra* note 83, at 60.

such that pharmacists are liable for more than merely dispensing errors.¹⁰⁰ Three sources have contributed to courts recognizing the expanded standard of care: (1) the pharmaceutical profession;¹⁰¹ (2) changes in pharmacy education;¹⁰² and (3) federal and state legislation.¹⁰³ New laws have swayed some courts to recognize that pharmacists play a role other than mere pill pushers.¹⁰⁴

In 1990, Congress enacted the Omnibus Budget Reconciliation Act ("OBRA"), which contained a provision requiring states to implement drug use review programs for Medicare recipients. The goal of OBRA was to "assure that prescriptions are appropriate, are medically necessary, and are not likely to result in adverse medical results."¹⁰⁵ Besides properly dispensing drugs, pharmacists were given new responsibilities—creating a prospective drug use review,¹⁰⁶ implementing a retrospective drug use review,¹⁰⁷ and attending educational programs.¹⁰⁸ To implement this legislation, state legislatures decided to expand

¹⁰⁰ See Asbury, *supra* note 91, at 907–08 (noting that changes in legislation, case law, and the pharmacists' role in health care have expanded the pharmacists' chances of being liable under "theories of strict liability, duty to warn, and breach of warranty").

¹⁰¹ In 1990, the term "pharmaceutical care" began to be used in the pharmacy field to indicate that the pharmacist plays a role in the implementation, monitoring, and therapeutic plans of patient health. See Fitzgerald, *supra* note 81, at 68; see also AM. COLL. OF LEGAL MED., LEGAL MEDICINE: LEGAL DYNAMICS OF MEDICAL ENCOUNTERS 563 (2d ed. 1991) (citing the influence of two nongovernmental organizations—The United States Pharmacopoeial Convention, Inc. and the Joint Commission on Accreditation of Health Organizations—in establishing pharmaceutical standards used by the courts to establish the standard of care (including the duty to warn)).

¹⁰² The emphasis in pharmacist training has moved away from understanding the chemical properties of drugs, compounding drugs, and referring patient questions to the physician toward patient-oriented care in which schools of pharmacy teach pharmacists how to communicate with patients and physicians. Myhra, *supra* note 83, at 61.

¹⁰³ *Id.* at 69; see also AM. COLL. OF LEGAL MED., *supra* note 101, at 561 (stating that twenty-two states in 1990 had statutes or regulations requiring pharmacists to counsel patients).

¹⁰⁴ See Kohl v. Am. Home Prods. Corp., 78 F. Supp. 2d 885, 891 (W.D. Ark. 1999) (looking at Arkansas' code to glean some "guidance" on the scope of pharmacists' standard of care); Hooks SupRx, Inc. v. McLaughlin, 642 N.E.2d 514, 518 (Ind. 1994) (turning to the Indiana code to determine the public policy regarding the pharmacists' duty in dispensing potentially addictive drugs).

¹⁰⁵ Fitzgerald, *supra* note 81, at 68.

¹⁰⁶ Prospective drug use review concerns patient-oriented services such as (1) screening for drug contraindications, interactions, and allergies; (2) patient counseling on how to take medication, common side effects, and refill information; and (3) creating and updating a patient profile. See Myhra, *supra* note 83, at 71–72.

¹⁰⁷ Retrospective drug use review entails a continual examination of records to identify fraud, abuse, and unnecessary medications. *Id.* at 72–73.

¹⁰⁸ OBRA's educational programs were aimed at improving, prescribing, and dispensing practice through drug use review boards whose missions were to educate doctors and pharmacists. See *id.* at 73–74.

these extra-drug dispensing duties beyond pharmacists who were ministering to Medicare patients. The states drafted "mini-OBRA" statutes, making these general job requirements for pharmacists.¹⁰⁹

With these new responsibilities, courts have expanded the standard of care, adding complexity to pharmacists' legal situation. Under the contemporary paradigm, a pharmacist who fails to warn of adverse drug interactions or of adverse side effects can be held liable for a patient's injury.¹¹⁰ As a result, pharmacists are wary of any methods or requirements that may expose them to further liability. Thus, the peer reviews, reporting systems, research, and self-monitoring systems have caused pharmacists to participate reluctantly in these procedures, if at all, because these systems are viewed as another means of expanding liability.¹¹¹ The pharmacists' rationale: why perform these techniques when litigants may use this information to advance their cases?¹¹²

V. DISCOVERY

To obtain records of pharmacists' dispensing errors in a lawsuit, injured patients would seek this information through discovery. For the plaintiff, obtaining these records is not difficult because the scope of discovery is so great,¹¹³ making it difficult for pharmacists to shield information regarding errors. All that is needed to obtain information in discovery is to show both that the requested documents are relevant to the claim and that the discovery of such documents are "reasonably calculated to lead to discovery of admissible

¹⁰⁹ *Id.* at 74; see also Fitzgerald, *supra* note 81, at 68.

¹¹⁰ See *Hooks SuperRx, Inc. v. McLaughlin*, 642 N.E.2d 514, 519 (Ind. 1994) (finding a duty for pharmacists to prevent patients from overusing prescription drugs); *Lasley v. Shrake's Country Club Pharmacy, Inc.*, 880 P.2d 1129, 1134 (Ariz. Ct. App. 1994) (holding that a pharmacist's standard of care "includes a responsibility to advise a customer of the addictive nature of a drug, to warn of the hazards of ingesting two or more drugs that adversely interact . . . , and to discuss with the physician the addictive nature of a prescribed drug").

¹¹¹ A debate exists in pharmacy circles regarding the type of error-monitoring system that should be put in place. Some call for a mandatory system whereby any error that occurs must be reported. Opponents fear that such mandatory reporting would harm pharmacists because the information would become discoverable. Also, there are financial and disciplinary penalties that result from mandatory reporting. The punitive elements and the potential for discovery contribute to a reluctance to create such mandatory systems. Therefore, the alternative is voluntary reporting, which has the advantage of confidentiality but does not provide the comprehensive reporting and examination of errors that a mandatory system would provide. At least with the voluntary system, information is confidential and some type of examination of errors can occur. See *Mandatory Reporting Programs*, *supra* note 14; *supra* notes 63-70.

¹¹² See *INST. OF MED.*, *supra* note 7, at 109 (recognizing that "[t]he potential for litigation may sometimes significantly influence the behavior of . . . health care providers").

¹¹³ See *FED. R. CIV. P.* 34(a) (permitting a party "to produce and . . . to inspect and copy, any designated documents" in the scope of Rule 26 and in the possession of the other party).

evidence.”¹¹⁴ Since any information about a pharmacist’s errors would be “relevant to the claim”¹¹⁵ of pharmacy error, pharmacists’ self-reported data, incident reports, and peer reviews would be discoverable. Treatises available to plaintiff’s counsel even instruct the attorney to inquire into such information when drafting interrogatories¹¹⁶ and conducting depositions.¹¹⁷ Therefore, pharmacists fear the implications of gathering error reports or participating in other procedures because they might reveal damaging information that could lead to liability or greater damages.¹¹⁸ Because of this danger of exposure to liability, various pharmacist interest groups have recommended that a means of shielding this information from the scope of discovery be statutorily developed.¹¹⁹ Otherwise, these groups argue, research into errors and improvements in patient

¹¹⁴ See Rule 26(b)(1) of the Federal Rule of Civil Procedure, which explains the scope of discovery by stating:

Parties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party, including the existence, description, nature, custody, condition, and location of any books, documents, or other tangible things and the identity and location of persons having knowledge of any discoverable matter. For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.

FED. R. CIV. P. 26(b)(1).

¹¹⁵ *Id.*; see also *Leon v. County of San Diego*, 202 F.R.D. 631, 634 (S.D. Cal. 2001) (stating that for information to be discoverable it must meet Rule 26’s threshold relevancy requirement).

¹¹⁶ See 4 BENDER’S FORMS OF DISCOVERY, *supra* note 12, at 546, 552, 555–58 (suggesting plaintiffs’ attorneys inquire into the following topics when conducting discovery into dispensing errors: (1) does the store keep a record of all prescriptions filled?; (2) how many other prescriptions were filled the day of the mistake?; (3) is there a regular filling procedure and did the pharmacist deviate from this procedure?; (4) does the pharmacist employ safeguards to avoid mistakes?; (5) has the pharmacist ever made a mistake in filling a prescription?; (6) what type of mistake was it, who did it involve, when did it happen, and how did it occur?; and (7) after implementing the prescription procedure, did a mistake occur?).

¹¹⁷ Laura M. Smalley, *Cause of Action Against Pharmacist for Injury or Death Caused by Prescription Drugs*, 13 CAUSES OF ACTION 2D 91, § 38, at 156–57 (1999) (instructing plaintiff’s counsel to seek a variety of information during discovery including: (1) whether prior complaints against the pharmacy have been filed; (2) whether the pharmacy has been involved in prior lawsuits; (3) whether there are records of prior complaints; and (4) whether the defendant admits liability for the actions because the defendant knew of adverse interactions with other drugs, failed to counsel the patient, or represented services that were not provided).

¹¹⁸ See *Harco Drugs, Inc. v. Holloway*, 669 So. 2d 878, 881 (Ala. 1995) (upholding punitive damages, in part, because pharmacy-error reports exhibited willful and wanton conduct).

¹¹⁹ See INST. OF MED., *supra* note 7, at 10 (recommending that Congress pass legislation to protect data regarding patient safety and quality improvement).

safety will be stifled because few will report errors or engage in monitoring out of fear that doing so will lead to liability in a lawsuit.¹²⁰

Though pharmacists want completely new laws to protect themselves from liability, legal recourse already exists that can provide some protection. To combat a claim for discovery of information about prior dispensing errors, the Federal Rules of Civil Procedure provide two sources of protection: (1) having the court limit the scope of discovery;¹²¹ or (2) finding an applicable privilege and asserting it.¹²² Neither option will give pharmacists absolute certainty of protection, but these are two avenues open to pharmacists. For pharmacists to successfully obtain from a court a ruling to limit discovery they would have to overcome the “normally predominant principle of utilizing all rational means for ascertaining the truth.”¹²³ The scope of discovery is “broad, perhaps the broadest

¹²⁰ *Id.*

¹²¹ FED. R. CIV. P. 26(b)(2). This rule states in part that:

The frequency or extent of use of the discovery methods otherwise permitted . . . shall be limited by the court if it determines that: (i) the discovery sought is unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity . . . to obtain the information sought; or (iii) the burden or expense of the proposed discovery outweighs its likely benefit

Id.; see also FED. R. CIV. P. 26(c) (permitting a court to grant a protective order as “justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense”). The protective order can shield information completely from discovery, or it can limit discovery’s time, place, method, and scope. *Id.*

¹²² FED. R. CIV. P. 26(b)(5). This rule states that:

When a party withholds information otherwise discoverable under these rules by claiming that it is privileged . . . the party shall make the claim expressly and shall describe the nature of the documents, communications, or things not produced or disclosed in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the applicability of the privilege or protection.

Id.; see also *Leon v. County of San Diego*, 202 F.R.D. 631, 634 (S.D. Cal. 2001) (noting that if the relevancy requirement threshold is met the court must permit discovery of the information unless a privilege is asserted).

¹²³ ROGER S. HAYDOCK & DAVID F. HERR, *DISCOVERY PRACTICE* § 2.1 (3d ed. 1996, updated through Supp. 2001) (quoting *Elkins v. United States*, 364 U.S. 206, 234 (1960)). But see John D. Lantos & Martha Montello, *Mistakes in Context*, in *MARGIN OF ERROR*, *supra* note 2, at 73, 75–76 (arguing that it is impossible to find truth in litigation because its methods of ascertaining truth are “notoriously funky and arcane”). Lantos and Montello opine that the process of fact-finding is a ritual that creates coherence for particular events, making disturbing events less disturbing. *Id.* Thus, the truth-finding process is really a means of reassuring people because the truth that is “found” is the one that makes the most sense, the one that corresponds with “conventional wisdom.” *Id.* Since the medical malpractice approach “imagines an ideal world in which all care is perfect,” any deviation is blamed on the individual. *Id.* In litigation, the fact-finder will discover a truth that focuses on the individual while ignoring a more complex truth because it defies conventional wisdom. *Id.*

ever permitted.”¹²⁴ However, since plaintiffs will be seeking information meant to be confidential, pharmacists may first request the court to limit discovery by filing a motion for a protective order, arguing that revealing this information will lead to annoyance or undue burden.¹²⁵ While it seems unlikely that an argument for removing information from the truth-finding forum of a litigation would be successful,¹²⁶ the pharmacist must remember that error-reducing activities will accomplish an important public policy—maintaining and protecting the public health and safety.¹²⁷ A court might find this policy argument sufficiently persuasive to grant a motion for a protective order to shield some or all confidential information. However, policy arguments are not limited to protective orders exclusively; they can also be helpful in the second way that information is shielded from discovery—asserting a privilege.

VI. PRIVILEGE

“The existence of a privilege is one of the few claims that will legitimately stonewall discovery inquiries.”¹²⁸ The following are the four sources of privileges: (1) the United States Constitution;¹²⁹ (2) Congressional or state legislative acts;¹³⁰ (3) Supreme Court rules;¹³¹ or (4) the common law.¹³² For

¹²⁴ CYCLOPEDIA OF FEDERAL PROCEDURE § 25.12 (3d ed., rev. vol. 2001); cf. *Capellupo v. FMC Corp.*, Civ. No. 4-85-1239, 1988 WL 41398, at *7 (D. Minn. May 3, 1988) (stating that discovery rules “are to be broadly and liberally construed”).

¹²⁵ FED. R. CIV. P. 26(b)(2) (permitting a court to limit the scope of discovery if: (1) “the discovery sought is unreasonably cumulative or duplicative”; (2) the party has had “ample opportunity to obtain the information sought” through discovery; or (3) “the burden or expense . . . outweighs its likely benefit”); see also Donald P. Vandegrift, *Legal Development: The Privilege of Self-Critical Analysis: A Survey of the Law*, 60 ALB. L. REV. 171, 188–89 (1996) (noting that a protective order might be an effective way to block discovery of some confidential information).

¹²⁶ But see Note, *Making Sense of Rules of Privilege Under the Structural (II) Logic of the Federal Rules of Evidence*, 105 HARV. L. REV. 1339, 1354–55 (1992) (stating that the Supreme Court believes Rule 26(c) to have the “potential to supplement or replace the formal privilege protections,” thereby permitting a court to block discovery of certain self-evaluative reports).

¹²⁷ See, e.g., *Brem v. DeCarlo*, 162 F.R.D. 94, 102 (D. Md. 1995) (recognizing an interest in quality healthcare); FED. R. EVID. 407 advisory committee’s note (stating that there is a “social policy of encouraging people to take . . . steps in furtherance of added safety”).

¹²⁸ HAYDOCK & HERR, *supra* note 123, § 2.1.

¹²⁹ Privileges embedded within the Constitution include the right to protect against self-incrimination and the right of privacy. *Id.* § 2.2.

¹³⁰ Among the Congressionally created privileges are: (1) accident reports; (2) trade secrets; (3) credit information; (4) statistics pertaining to cotton, tobacco, peanuts, and housing; (5) national defense and security; and (6) accountant-client communications. *Id.* § 2.3. States have extended privileges to protect such subjects as teacher-student relationships, social service-juvenile offender interactions, hospital and medical review committees, scholarly research, newspapers’ confidential sources, and tax returns. *Id.* § 2.6.

pharmacists to assert a privilege barring the discovery of information obtained through error-identification methods, the most likely sources of such a privilege would be an act of Congress, state legislation, or the common law.¹³³ These three sources have considered and adopted privileges that encompass some of the methods aimed at reducing pharmacy errors. From the pharmacists' perspective, the result is a patchwork of protection that is wholly insufficient and too complex because it provides no assurance of protection from liability. However, since some form of protection exists, pharmacists should not spurn these error-identification and reduction methods.

A. Congressional Legislation¹³⁴

Congress may explicitly create privileges by passing statutes that bar discovery of certain information.¹³⁵ Lobbyists for pharmacists on Capitol Hill have attempted to get legislation passed protecting error reports from discovery. So far, their work in the Senate has resulted in the drafting of two bills that were referred to the Committee on Health, Education, Labor, and Pensions on June 15, 2000. Both bills had essentially the same purpose of establishing "a national voluntary [reporting] system to continually reduce medical errors, and improve

¹³¹ Trial preparatory materials and attorney work product are two examples of privileges created by the Supreme Court. *Id.* § 2.4.

¹³² Courts have given privileges in the following areas: attorney-client meetings, psychotherapist-patient therapy sessions, clergy-parishioner confessions, spousal relationships, trade secrets, and certain government activities. *Id.* § 2.5.

¹³³ See Richard L. Kaiser, Comment, *The Self-Critical Analysis Privilege for Products Liability: What Is It, and How Can It Be Achieved in Wisconsin?*, 1999 WIS. L. REV. 119, 143 (stating that the ways to adopt a privilege are by statute or by common law).

¹³⁴ While Congress is considering certain legislation to shield pharmacists from liability if they report to certain sanctioned reporting systems, the executive branch has been active in advocating a confidential reporting system. Members of the Bush Cabinet have testified before the Senate Health, Education, Labor, and Pensions Committee, requesting that Congress create a reporting system. Treasury Secretary Robert O'Neill stated: "[i]t must be safe to learn from errors. This is a fundamental requirement for improvement. Punishment, ridicule and legal exposure drive reporting underground so learning does not occur." *Patient Safety*, *supra* note 64, at 47. Secretary of Health and Human Services Tommy Thompson reiterated Secretary O'Neill's statements when he said "confidentiality of the data collected is essential." *Id.* at 50. Also, the Health and Human Services Department has established a Task Force to integrate data collection on medical errors, coordinate research, and promote collaboration in reducing the incidence of injuries resulting from medical errors. See Press Release, U.S. Dept. of Health and Human Services, Secretary Thompson Announces HHS Patient Safety Task Force, at <http://www.ahrq.gov/news/press/pr2001/pstfpr.htm> (Apr. 23, 2001).

¹³⁵ HAYDOCK & HERR, *supra* note 123, § 2.3. Examples of information that Congress has shielded from discovery include: accident reports, trade secrets, credit agency information, identification of an informer, and certain census data. *Id.*

patient safety to ensure that individuals receive the highest quality health care.”¹³⁶ To guarantee maximum reporting, the bills contained legal protections that would have shielded the reported information from discovery.¹³⁷ However, these bills never surfaced from committee amidst disagreements over what legal protections to grant providers who submit information.¹³⁸ Also, the House of Representatives drafted its own version of an error-reporting bill with similar confidentiality statements that also failed to survive committee.¹³⁹ Since shielding error reporting is a controversial issue, passing such a voluntary reporting system may be difficult, as Congress receives pressure from patient-rights groups who oppose such protections. These failed attempts suggest that if pharmacists are going to expend resources to obtain federal legislation protecting them from liability, they will confront opposition.

B. *The State Legislatures*¹⁴⁰

Though Congressional activity to create a privilege or immunity from discovery has stalled, some state legislatures have been active in creating privileges for pharmacists in the peer review committee context.¹⁴¹ A search of

¹³⁶ S. 2743, 106th Cong. § 2 (2000); *see also* S. 2738, 106th Cong. § 2 (2000) (stressing a similar aim in its purpose section).

¹³⁷ S. 2743, § 927(a)–(b) (containing the confidentiality portion of the bill, which makes “information developed in connection with the Voluntary Reporting System or the Surveillance System” privileged and confidential as well as evidence of a report that has been submitted to either system, but not the facts surrounding the error); *see also* S. 2738, § 925(a)–(c) (containing a confidentiality provision that applies to “any data, reports, records, memoranda, analyses, statements, and other communications” found in: (1) reports to a “National Patient Safety Database”; (2) peer review proceedings; and (3) research on methods of medical error reporting).

¹³⁸ Am. Soc’y of Health Sys. Pharmacists, *ASHP Government Affairs: Legislative Issues Summary*, at http://www.ashp.org/public/proad/legislative/September_2001.html (Sept. 2001).

¹³⁹ Medication Error Prevention Act of 2000, H.R. 3672, 106th Cong. § 247(a), (d), (e) (2000).

¹⁴⁰ Various organizations have examined whether state legislative activity has resulted in the implementation of statutes to protect and to reduce medical errors. The Institutes of Medicine found that twenty-one states have established mandatory reporting systems for medical errors while a National Conference of State Legislatures survey uncovered twenty-one states that have implemented programs to reduce medical errors, including reporting and quality improvement programs. Finally, the National Academy for State Health Policy reported that fifteen states have voluntary reporting for medical errors. While not all of these state statutes deal with pharmacy errors, they do show the states’ interest in reducing medical errors generally. *See* Nat’l Conference of State Legislatures, *AFI Health Committee: Issues in Brief*, at <http://www.ncsl.org/statefed/health/mederrrib.htm> (Aug. 1, 2000).

¹⁴¹ Searches of state legislation on Lexis and Westlaw reveal that at least eight states provide some protection for information on pharmacist errors, at least when this information is submitted to a peer review panel. *See* FLA. STAT. ANN. § 766.101 (West 2001) (shielding

state law reveal that eight states have protected pharmacists' peer review committee information from discovery,¹⁴² yet these statutes do not necessarily grant protection to all error reduction methods. Instead, the state privileges only protect certain, narrow bands of information, leaving gaps in coverage. For instance, while self-review of one's actions is viewed as an important aspect in the quest for reducing errors,¹⁴³ these statutes will not shield this self-monitoring process because they primarily apply to peer reviews. Therefore, without similar protection, it is unlikely that pharmacists would willingly maintain self-monitoring records, even if these records were to lower incidents of error, because pharmacists would believe that the reports could expose them to liability.

Besides self-monitoring, another method of reducing and identifying pharmacy errors is through research,¹⁴⁴ yet only one statute provides any protection—section 565.055 of the Texas Occupational Code. This law permits the release of data from Texas Board of Pharmacy investigations on pharmacy errors to “a person engaged in bona fide research, if all information identifying a specific individual has been deleted,”¹⁴⁵ permitting these data to be used in research. Thus, the statute serves a dual purpose. First, it encourages the release of

medical review committee reports, which include pharmacists, from discovery); KAN. STAT. ANN. § 65-1627(b) (2000); MD. CODE ANN., HEALTH OCC. § 12-318(c) (2001) (barring any information used by a pharmacy review committee from discovery); MO. ANN. STAT. § 537.035(4) (West 2001) (protecting “the proceedings, findings, deliberations, reports, and minutes of peer review committees” from discovery); Act of May 17, 2001, ch. 120, 2001 Minn. Laws 560 (amending sections 145.61, subdivision 5, and 145.64, subdivision 1, by maintaining the confidentiality of review organizations' information); TENN. CODE ANN. § 63-10-605 (2001) (making information, reports, and findings of peer review committees confidential); TEX. OCC. CODE ANN. § 564.103 (Vernon 2001) (keeping peer review committee records confidential); TEX. OCC. CODE ANN. § 565.055 (Vernon 2001) (shielding information compiled by a Texas Pharmacy Board's investigation from discovery); WASH. REV. CODE ANN. § 4.24.250 (West 2001) (establishing immunity from discovery to peer review proceedings and reports).

¹⁴² Not every statute has a pharmacist-friendly tone as state legislatures are also interested in devising methods to protect the public. Some state legislatures have proposed bills requiring pharmacists to report dispensing errors to government health agencies. See H.B. 813/S.B. 1096, 2001 Leg., 103d Sess. (Fla. 2001), *summary available at* http://www.ashp.org/public/proad/state/December_2001.html#F. Others have proposed legislation that makes it a misdemeanor to fail to disclose a pharmacy error to a patient. See N.Y. A06945, 224th Gen. Assemb., (N.Y. 2001), *summary available at* http://www.ashp.org/public/proad/state/December_2001.html#F. In the Massachusetts Senate, a bill is pending that would grant the Massachusetts Board of Registration in Pharmacy the power to discipline pharmacists by fining them up to \$5000, ordering community service, or requiring additional training. This legislation was proposed because some in the Massachusetts community viewed the present disciplinary system of censure or license revocation as being ineffective. Raja Mishra, *Pharmacies Oppose Bill to Fine for Drug Errors*, BOSTON GLOBE, Jan. 3, 2002, at B1.

¹⁴³ See Grasha, *supra* note 13, at 9–10.

¹⁴⁴ See *supra* notes 71–72 and accompanying text.

¹⁴⁵ § 565.055(c)(5).

peer review data, and second, it allows for valuable research on pharmacy errors to be conducted. Through these twin goals, the statute addresses and reconciles two sets of concerns—those pertaining to patient health and those dealing with increased liability and loss of confidentiality.

While the Texas statute grants some protection, it fails to protect certain types of error reduction methods, including self-monitoring.¹⁴⁶ The statute exemplifies the complexity of the pharmacy error issue because its limited protection may make pharmacists reluctant to take certain actions, which in turn may cause the patients' health to suffer.

C. *The Common Law*¹⁴⁷

While pharmacists would prefer the certain protection afforded by state statutes, these legislative acts create complexity because they do not apply to all the information that pharmacists want shielded from discovery.¹⁴⁸ Though the statutes generally only protect peer review, the common law can extend protection for pharmacists who examine errors by creating other privileges.¹⁴⁹ Before a court considers whether information or evidence is protected by a privilege, the court must find the following four elements to exist: (1) the communication must originally be confidential; (2) this confidentiality is an essential reason for maintaining a relationship between individuals or for "serving a vital governmental or public need"; (3) the public must view this relationship or need as necessary; and (4) the disclosure of the information would injure one party more than it would benefit the other.¹⁵⁰ However, even with these four

¹⁴⁶ See Grasha, *supra* note 13, at 10, 16.

¹⁴⁷ State and federal common law do not coincide in the area of privilege. Where a case is being heard under pendent state and federal claims, a federal court will apply the federal common law privileges, not the state's, even if this results in ignoring an important state policy. See *Leon v. County of San Diego*, 202 F.R.D. 631, 635–37, (S.D. Cal. 2001) (stating that to apply state law in a federal case would "do harm to federal substantive and procedural policy").

¹⁴⁸ See *supra* notes 140–46 and accompanying text.

¹⁴⁹ See *supra* note 132 (listing privileges recognized by courts).

¹⁵⁰ HAYDOCK & HERR, *supra* note 123, § 2.1 (enumerating the four elements necessary for a privilege to be recognized). But see Note, *supra* note 126, at 1339–51, 1358. In the Note, the author argues that privilege should be divided into two categories—relational and action—which would lead to two different types of protection in the litigation process depending on the nature of the privilege claim. *Id.* at 1341–42. Relational privileges would be those confidential communications that emanate from "particular relationships" such as attorney-client or between spouses, which society has an interest in keeping confidential. *Id.* at 1341. Under Federal Rule of Evidence 501, these relational privileges would be immune from discovery except in exceptional circumstances. *Id.* at 1341–42, 1343–45. However, the second category of privileges—the activity privileges—would have no immunity from discovery and would only be shielded from admissibility at trial. These action privileges protect extrinsic actions that public policy deems to be sufficiently important to deserve a limited form of protection. Action

elements established, a court will not automatically find a privilege exists. Instead, a court will determine whether it is proper to grant the privilege, which does not always occur.¹⁵¹ If a court does find the circumstances to be appropriate for granting protection in the context of pharmacy error investigations, two common law options exist—the self-critical analysis privilege and the peer review privilege.

1. *Self-Critical Analysis Privilege*

The self-critical analysis privilege¹⁵² (also known as the self-evaluative privilege)¹⁵³ is one potential avenue to protect pharmacists' error-identification and reduction activities from being discoverable. Pharmacists have an interest in this privilege because it seems to encompass self-monitoring, incident reports, peer reviews, and reporting errors. When this privilege is invoked, the party seeking protection from disclosure asserts that critical self-study has been performed as "a review of a major policy or procedure . . . to permit the

privileges recognized on the federal level can be found in Federal Rules 407 (remedial measures), 408 (evidence of compromise or offer to compromise), and 409 (offer to pay medical expenses). *Id.* at 1342, 1345–49. Since the present privileging system does not allow for an expansion of the activity privileges, courts examine all new privileges under Federal Rule 501, creating, the author argues, an illogical system of forming privileges. *Id.* at 1339, 1349–51, 1358.

¹⁵¹ See *Univ. of Pa. v. EEOC*, 493 U.S. 182, 189 (1990) (stating that if a privilege "contravene[s] the fundamental principle that 'the public . . . has a right to every man's evidence' then the privilege should 'be strictly construed'" (quoting *Trammel v. United States*, 445 U.S. 40, 50 (1980))).

¹⁵² A district court in the District of Columbia first recognized this privilege in 1970. Though the court did not specifically call the privilege the self-critical analysis privilege, it recognized that "all communications originating [in a hospital peer review committee] are to be confidential" because the value of "improvement, through self-analysis, of the efficiency of medical procedures and techniques. . . . would be destroyed if the meetings and the names of those participating were to be opened to the discovery process." *Bredice v. Doctors Hosp., Inc.*, 50 F.R.D. 249, 250 (D.D.C. 1970). Thus, the court found a privilege for retrospective medical reviews aimed at self-improvement. *Id.* at 251. From this humble beginning for hospital peer reviews as a privilege, the privilege has expanded to encompass self-analysis reports in other disciplines, so there is no reason that this privilege could not cover monitoring in the pharmacy setting. See *Reichhold Chems., Inc. v. Textron, Inc.*, 157 F.R.D. 522, 525 (N.D. Fla. 1994) (reporting that courts have applied the self-critical analysis to accounting records, securities law, academic peer reviews, railroad accident investigations, product safety reports, and products liability); see also *United States ex rel. Sanders v. Allison Engine Co., Inc.*, 196 F.R.D. 310, 313 (S.D. Ohio 2000) (stating that some courts have found the privilege to apply in medical malpractice cases, police shooting investigations, and industrial accident reviews); *Bundy v. Sinopoli*, 580 A.2d 1101, 1105–06 (N.J. Super. Ct. Law Div. 1990) (reporting that New Jersey courts have recognized this privilege because "[p]ublic policy" demands the privilege in the areas of corporate records and health care).

¹⁵³ *Sanders*, 196 F.R.D. at 312.

evaluation and improvement of an organization's operations."¹⁵⁴ Without the protection of this privilege, a party would be compelled to disclose "documents containing honest self-evaluations which may contain potentially damaging information."¹⁵⁵

Before a court decides whether to apply the self-critical analysis privilege, it must first consider whether the party asserting the privilege waived it.¹⁵⁶ If no waiver has occurred, the court then examines whether the following four elements exist: (1) the information is intended to be confidential and to remain confidential;¹⁵⁷ (2) the party claiming the privilege asserts that the information comes from a self-critical analysis; (3) the free-flow of information would be curtailed if discovery were permitted; and (4) the public has a strong interest in preserving the free flow of information from this self-analysis.¹⁵⁸ If these elements are present, a court then weighs the interest in maintaining confidentiality with a competing interest—the public's need for all available evidence.¹⁵⁹ Some courts also try to determine whether the legislature has debated the privilege.¹⁶⁰ A court would grant the self-critical analysis privilege if it found both that disclosure would have an "undue chilling effect"¹⁶¹ and that the legislature had not rejected such a privilege. Since courts have decided to grant this privilege in limited circumstances, their confined application of the privilege suggests that a party will have difficulty demonstrating the primacy of the

¹⁵⁴ James F. Flanagan, *Rejecting a General Privilege for Self-Critical Analyses*, 51 GEO. WASH. L. REV. 551, 556 (1983) (defining self-critical analysis).

¹⁵⁵ Kaiser, *supra* note 133, at 122 n.10; *see also Sanders*, 196 F.R.D. at 312 (stating one rationale for the self-critical analysis privilege is to alleviate any fears that open and honest critiques will later be exposed in a court of law).

¹⁵⁶ *See Moloney v. United States*, 204 F.R.D. 16, 21 (D. Mass. 2001) (denying a self-critical analysis privilege claim because counsel did not timely, expressly, or concisely assert the privilege); *Bergman v. Kemp*, 97 F.R.D. 413, 416 (W.D. Mich. 1983) (explaining that this privilege is not absolute because a party can waive it by voluntary disclosure).

¹⁵⁷ Kaiser, *supra* note 133, at 124.

¹⁵⁸ Note, *The Privilege of Self-Critical Analysis*, 96 HARV. L. REV. 1083, 1086 (1983).

¹⁵⁹ *Id.* at 1084.

¹⁶⁰ *See Univ. of Pa. v. EEOC*, 493 U.S. 182, 189 (1990) (ruling that the Court will not recognize a privilege where Congress has already considered, but not adopted, a privilege); *Cryer v. Corbett*, 814 So. 2d 239, 249 (Ala. 2001) (refusing to revisit whether a self-critical analysis should exist because the "[l]egislature . . . has already addressed the issue of confidentiality of certain records maintained by healthcare providers"); *DeMoss Rexall Drugs v. Dobson*, 540 N.E.2d 655, 657 (Ind. Ct. App. 1989) (denying recognition of the self-critical analysis because "all privileges are statutory in nature in Indiana," meaning that the court leaves "the determination of this state's public policy . . . to the General Assembly"); *In re Parkway Manor Healthcare Ctr.*, 448 N.W.2d 116, 121 (Minn. Ct. App. 1989) (recognizing that the failure of the legislature to recognize the self-evaluation privilege for certain entities "is strong evidence of its intent not to extend the privilege").

¹⁶¹ *Bergman*, 97 F.R.D. at 418.

confidentiality of the self-critical analysis over the public's right to this information. Therefore, the presence of some chilling effect is not always viewed as a compelling reason to grant the privilege.¹⁶²

Even if a court recognizes the self-critical analysis privilege, this privilege will not always shield all aspects of self-critical reports.¹⁶³ Thus, it is a limited privilege for the following five reasons. First, it protects subjective material such as opinions and assessments of an individual's skill and competence, not facts that led to an evaluation.¹⁶⁴ Second, it is a limited privilege in the sense that a party can waive it.¹⁶⁵ While the privilege may exist, it is not an absolute guarantee of protection. Third, if the privilege were recognized on the state level, it would not automatically be recognized on the federal level in a case with both federal and state claims.¹⁶⁶ Therefore, even when a state has either explicitly codified a privilege or developed a particular common law privilege, the federal court is under no obligation to follow the state policy expressed in the privilege.¹⁶⁷ However, if a federal court believes that denying this privilege will inhibit confidentiality, ignore public policy favoring health care, or thwart the purpose of

¹⁶² See Kaiser, *supra* note 133, at 134–35 (explaining that because courts determine the basis of the privilege on a case-by-case basis, the privilege has not been universally accepted, garnering only spotty acceptance among courts); see also *Holland v. Muscatine Gen. Hosp.*, 971 F. Supp. 385, 390 (S.D. Iowa 1997) (observing that the privilege “has had an ambiguous existence, neither uniformly adopted nor rejected”); *Reid v. Lockheed Martin Aeronautics Co.*, 199 F.R.D. 379, 382 (N.D. Ga. 2001) (observing that the Supreme Court and circuit courts have “neither definitively denied the existence of such a privilege, nor accepted it and defined its scope”) (quoting *Dowling v. Am. Haw. Cruises, Inc.*, 971 F.2d 423, 425 n.1 (9th Cir. 1992)).

¹⁶³ See *United States ex rel. Sanders v. Allison Engine Co., Inc.*, 196 F.R.D. 310, 315 (S.D. Ohio 2000) (stating that the self-evaluative privilege is “qualified” and that “it can be overcome by showing extraordinary circumstances or special need”).

¹⁶⁴ Flanagan, *supra* note 154, at 556, 562.

¹⁶⁵ See *Moloney v. United States*, 204 F.R.D. 16, 21 (D. Mass. 2001). In *Moloney*, the court dismissed counsel's arguments that the self-critical analysis and other privileges should shield conversations concerning a patient's care. Instead of asserting the self-critical analysis privilege during the deposition, the attorney chose to rely on attorney-client and work product privileges. It was only during the evidentiary hearing that counsel asserted the self-critical analysis privilege. This delay led the court to rebuke counsel for failing to assert this privilege in a timely or concise manner as required by Federal Rules of Civil Procedure 26(b)(5) and 30(d)(1).

¹⁶⁶ See *Holland*, 971 F. Supp. at 391 (holding that “[w]here an action involving primarily federal law includes pendent state law claims, the existence and scope of a claimed privilege is governed by the federal rules”). But see *Brem v. DeCarlo*, 162 F.R.D. 94, 102 (D. Md. 1995) (holding that “the purpose of the Maryland medical review committee statute of improving the quality of health care would be thwarted if confidentiality . . . were not protected [and] the public interest in promoting quality health care outweighs the . . . purported need for the information”).

¹⁶⁷ See *Holland*, 971 F. Supp. at 388 (stating that the existence of state privileges “is not conclusive in an action brought in federal court under federal law”).

a state statute, it may recognize the state policy as a federal common law privilege.¹⁶⁸ Fourth, the privilege can be overcome by a showing of necessity by the party.¹⁶⁹

Finally, on the federal level, the privilege is not absolute because it is grounded in Federal Rule of Evidence 501.¹⁷⁰ This rule requires that every new privilege claim be analyzed on a case-by-case basis.¹⁷¹ Therefore, if and when a jurisdiction has recognized the self-critical analysis privilege's existence,¹⁷² courts in that jurisdiction still must examine every subsequent claim of privilege individually. In some instances, a court might grant the privilege, while in others

¹⁶⁸ See *Brem*, 162 F.R.D. at 102 (recognizing the existence of the self-critical analysis privilege because "the Maryland statute evidences a strong public policy commitment to protect the confidentiality of [peer review] information").

¹⁶⁹ Flanagan, *supra* note 154, at 557 (observing that the self-critical analysis privilege is qualified because it can be defeated "by a demonstration of necessity").

¹⁷⁰ *Univ. of Pa. v. EEOC*, 493 U.S. 182, 188 (1990). Federal Rule of Evidence 501 states:

Except as otherwise required by the Constitution of the United States or provided by Act of Congress or in rules prescribed by the Supreme Court pursuant to statutory authority, the privilege of a witness, person, government, State, or political subdivision thereof shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and experience. However, in civil actions and proceedings, with respect to an element of a claim or defense as to which State law supplies the rule of decision, the privilege of a witness, person, government, State, or political subdivision thereof shall be determined in accordance with State law.

FED. R. EVID. 501.

Therefore, for a privilege to be recognized in a federal case, it must be "established through the federal common law." *Price v. County of San Diego*, 165 F.R.D. 614, 617 (S.D. Cal. 1996). Also, without any discussion of specific privileges, the Rule gives courts "the flexibility to develop rules of privilege on a case-by-case basis." *Capellupo v. FMC Corp.*, Civ. No. 4-85-1239, 1988 WL 41398, at *2 (D. Minn. May 3, 1988) (quoting 120 CONG. REC. 40, 891 (1974) (statement of Rep. Hungate)). But see Note, *supra* note 126, at 1351-55 (arguing that the self-critical analysis privilege does not fit under Rule 501's "relational" privilege framework and that it makes sense to place it under the more limited "activity" privilege of Rule 407).

¹⁷¹ It should be noted that some state courts have also adopted a privilege for self-critical analysis. See *Reichhold Chems., Inc. v. Textron, Inc.*, 157 F.R.D. 522, 528 (N.D. Fla. 1994) (noting that Florida courts have adopted the privilege "not as a rule of privilege, but as a discretionary right of a court on grounds of public policy"); see also *Cryer v. Corbett*, 814 So. 2d 239, 249 (Ala. 2001) (conceding that the court has given "some recognition" to the self-critical analysis privilege for corporate records); *Bundy v. Sinopoli*, 580 A.2d 1101, 1105 (N.J. Super. Ct. Law Div. 1990) (stating that "[p]ublic policy dictates that the Court must in certain areas recognize the privilege of self-critical analysis").

¹⁷² In *University of Pennsylvania v. EEOC*, 493 U.S. at 189, 195, the Supreme Court refused to recognize the self-critical analysis privilege in an academic peer review context because (1) Congress had considered such a privilege but did not adopt it, and (2) this privilege had no deep "historical or statutory basis."

the court may refuse. As a result, pharmacists have no guarantee that a court would shield their self-monitoring information.

Two cases demonstrate the danger posed to pharmacists when self-evaluative reports are admitted into court because these reports of previous dispensing errors facilitated the award of punitive damages. In the first case, *McClure v. Walgreen Co.*,¹⁷³ an Iowa jury awarded the plaintiff both compensatory and punitive damages, which the defendant pharmacy appealed in part because the court admitted pharmacy error incident reports into evidence.¹⁷⁴ Although the defendant's argument was based on an evidentiary analysis, not a claim of privilege (i.e., the pharmacy believed there was insufficient evidence to establish punitive damages),¹⁷⁵ the case demonstrates why pharmacists and their employers fear discovery and admissibility of these incident reports—they help to establish not only simple negligence but the “willful and wanton disregard for the rights or safety of another,”¹⁷⁶ necessary to award punitive damages. Although the purpose of these reports was to examine why these errors occurred, coloring them with the aura of self-evaluation, they received no privilege. Thus, *McClure* demonstrates one danger of a court's not recognizing a privilege and allowing these reports to enter evidence—punitive damages may result.

In the second case, *Harco Drugs, Inc. v. Holloway*,¹⁷⁷ a pharmacy admitted to negligence after one of its pharmacists mistakenly filled a prescription for a cancer-fighting drug with an anti-arrhythmia medication. When the jury awarded both compensatory and punitive damages, the defendant drugstore appealed, arguing that the trial court committed reversible error by admitting into evidence 233 incident reports that the pharmacy had compiled over a three-year period. The Alabama Supreme Court believed this information was relevant because it indicated a failure “to initiate sufficient institutional controls over the manner in which prescriptions were filled,”¹⁷⁸ so it upheld the jury award.

The dissenting opinion reflected the concerns that pharmacists have for

¹⁷³ 613 N.W.2d 225 (Iowa 2000). In *McClure*, a woman undergoing chemotherapy had her prescription for Pepcid (a stomach acid reducing drug) improperly filled with Paxil (a medication for obsessive-compulsive disorder), leading to dizziness, confusion, nausea, and mental changes. After two falls, which respectively led to a broken right leg and left foot and an injured back, pelvis, and head, the plaintiff sued the pharmacy for negligence because of the dispensing error and the failure to warn of the severe withdrawal symptoms that resulted from being suddenly removed from Paxil. *Id.* at 228–30.

¹⁷⁴ *Id.* at 230. These incident reports contained information on similar dispensing errors that occurred in the same Walgreen pharmacy, which the court believed allowed a jury to “reasonably infer that Walgreen had a serious problem in this regard, knew it had the problem, but did not take adequate steps to correct it.” *Id.* at 231.

¹⁷⁵ *Id.* at 230.

¹⁷⁶ *Id.* at 230 (quoting IOWA CODE § 668A.1 (1997)).

¹⁷⁷ 669 So. 2d 878, 879–81 (Ala. 1995).

¹⁷⁸ *Id.* at 881.

engaging in self-critical analyses. First, the dissenting judge feared that “[t]his holding of admissibility may tend to stifle self-review and efforts to improve a company’s safety for fear that the very process of considering alternatives will make the failure to adopt them present a jury question of wantonness.”¹⁷⁹ Also, the dissent noted that the pharmacy had filled over two million prescriptions during the three-year period in which the 233 incident reports were recorded, creating a .0016% error rate.¹⁸⁰ Such a low percentage, the dissent believed, did not warrant a finding of wantonness.¹⁸¹ *Harco Drugs* once again demonstrates that attempts to decrease errors by self-analysis may lead to punitive damages. These two cases demonstrate why recognition of a self-critical analysis privilege is important for pharmacists—without it, self-evaluative information will enter into evidence and become useful in showing liability sufficient for proving not only negligence, but also recklessness.

Although these two cases show the dangers of the self-critical analysis privilege not being applied, neither case is helpful in determining whether it would apply in the context of pharmacy error because defendants’ counsel did not assert the privilege. Therefore, this privilege remains a possible shield of self-critical information from discovery. However, it is unsettled which courts recognize this privilege, or whether these self-evaluations meet all four criteria that comprise the self-critical analysis privilege.¹⁸² Three of the criteria necessary for the privilege appear to be met.¹⁸³ First, pharmacists intend for the information to be confidential. Second, pharmacists’ examination or reporting of their errors would be a form of self-critical analysis. Third, releasing the information would curtail its collection and analysis (because pharmacists would fear liability).

If these were the only three criteria necessary, a court might grant the privilege, but the law requires a fourth element that complicates the analysis—the necessity that the public have a strong interest in maintaining this information’s confidentiality. This last element requires that a judge make a decision on this “clash between highly valued interests”¹⁸⁴—whether the public should have access to all relevant information when filing a lawsuit¹⁸⁵ or whether the

¹⁷⁹ *Id.* at 883 (Almon, J., dissenting). The dissent, therefore, believed that an undue chilling effect would result.

¹⁸⁰ *Id.*

¹⁸¹ *Id.* at 884.

¹⁸² See *supra* notes 157–59 and accompanying text (stating that the four criteria are: (1) the information comes from a self-critical analysis; (2) the public has a strong interest in preserving the continuation of the self-critical analysis; (3) the incentive to maintain the information would be curtailed if it were open to discovery; and (4) the information is intended to be confidential).

¹⁸³ See *supra* notes 157–58 and accompanying text.

¹⁸⁴ *Bergman v. Kemp*, 97 F.R.D. 413, 417 (W.D. Mich. 1983) (quoting *O’Connor v. Chrysler Corp.*, 86 F.R.D. 211, 218 (D. Mass 1980)).

¹⁸⁵ The value of information from a self-critical analysis to the plaintiff is that it can aid in

pharmacist and pharmacy should be protected from releasing self-evaluations that could contain damaging information.

Some courts have indicated that they would find this fourth criterion to weigh in favor of confidentiality when the party has engaged in post-accident analysis (as opposed to pre-accident analysis).¹⁸⁶ In the cases of self-monitoring, incident reports, and pharmacist reporting, their purpose is to note and examine errors *after* they occur, engaging pharmacists in post-accident analyses.¹⁸⁷ It follows that these error-monitoring and reduction activities should have protection under the self-critical analysis privilege (where it is recognized) because self-monitoring can only occur after an error.

Court will protect a post-accident analysis because it implies a special situation or a limited circumstance. However, protection might not be granted if self-monitoring were viewed as a standard practice used to prevent errors before they occur.¹⁸⁸ While self-evaluation is a post-event activity for one specific error, it could also be viewed as a regular activity because such self-analysis would occur regularly after every event. Since its cumulative effect is to identify and analyze errors whenever they occur, the post-accident status of previous self-evaluative reports could fall within the category of regular and normal activity in the course of business, opening these reports to discovery or admissibility when later errors occur. Once this accumulated data of errors becomes discoverable, this information may contribute to juries finding pharmacists or pharmacies negligent because they were on notice of errors but seemingly failed to act when the errors continued.¹⁸⁹

identifying potential witnesses, show the decision making process of an individual, and reveal whether errors are a common activity. See Flanagan, *supra* note 154, at 557–58; see also *Reichhold Chems., Inc. v. Textron, Inc.*, 157 F.R.D. 522, 524 (N.D. Fla. 1994) (explaining that these self-analyses “creat[e] a self-incriminating record that may be evidence of liability”).

¹⁸⁶ *Reichhold Chems.*, 157 F.R.D. at 527 (commenting that the “difference between pre-accident and post-accident analysis . . . is of vital importance”).

¹⁸⁷ The *Reichhold Chemicals* court noted that retrospective analysis is not relevant to claims of negligence. Therefore, shielding this information from discovery should have no bearing on a plaintiff’s case; however, by refusing to make these evaluations confidential, courts would have a chilling effect on conducting these analyses, which presumably would delay safety improvements. *Id.* This delay in safety evaluations is viewed as strongly weighing in favor of confidentiality because this is the same policy found in Federal Rule of Evidence 407. *Id.* at 524; see also *supra* Part V.

¹⁸⁸ See *Leon v. County of San Diego*, 202 F.R.D. 631, 637 (S.D. Cal. 2001). This case examines safety reviews in terms of whether they fit within the policy of Federal Rule of Evidence 407 for excluding evidence of remedial measures. To encourage entities to engage in safe practices, safety reviews conducted after an accident are protected. By airing this information in the courtroom, courts fear that a chilling effect will occur. However where the reviews occur prior to an accident and are part of a regular course of activity, they are not excluded from evidence because such reviews do not implicate the same policy concerns as post-accident reports. *Id.*

¹⁸⁹ See *Harco Drugs, Inc. v. Holloway*, 669 So. 2d 878 (Ala. 1995) (upholding a punitive

Instead of examining whether a self-analysis has post-accident status, other courts might follow a separate line of reasoning, citing policy concerns. These courts could hold pharmacists accountable for their actions.¹⁹⁰ When pharmacists' negligent actions injure individuals, the public does not want to shield error reduction methods because these reports are useful in proving that the pharmacists' actions are negligent and maybe even willful and wanton—the requirement for punitive damages.¹⁹¹ The injured public has a right to be compensated, provided it meets certain legal requirements. Therefore, no matter what level of protection pharmacists have to shield information tied to reducing errors, pharmacists will never be completely protected from liability after a pharmacy error occurs. While peer reviews and self-monitoring reports may help a plaintiff show negligence, they are not necessary because the patient will have other facts and documents to rely on, including the serious injury that resulted from the dispensing error.¹⁹² Therefore, the public need not fear that exposing the information to discovery will dramatically increase the likelihood of an individual falling victim to pharmacy error. Pharmacists still have an incentive to reduce errors, which are the sole reason for being subjected to court proceedings. (They are not on trial for using various methods for reducing errors.)¹⁹³ Courts will find pharmacists liable because they have breached a duty that caused injury, not because they collected and analyzed certain information about errors.

However, if a court were to grant this privilege, pharmacists would have a greater incentive to use and develop error-reduction methods, and they would have the tools available both to help them learn why errors occurred and to discover how to reduce errors.¹⁹⁴ Since these dispensing errors have potential life-threatening implications, authorities believe that the collection of error data is

damage award in part because the jury's decision was based on thirty-two incident reports detailing pharmacist dispensing errors, which showed that the pharmacy was aware of errors).

¹⁹⁰ See *McClure v. Walgreen Co.*, 613 N.W.2d 225, 231 (Iowa 2000) (chastising the defendant pharmacy for its "egregious . . . failure to warn" a patient of adverse side effects, which caused the court in part to uphold punitive damages against the pharmacy).

¹⁹¹ See *Harco Drugs, Inc.*, 669 So. 2d at 878 (upholding a jury's award of punitive damages arising out of a claim against a pharmacist's dispensing error).

¹⁹² The four elements of negligence will be present whether or not a pharmacist engages in self-monitoring. The duty will remain. By making a dispensing error, there will be a breach of the duty. See Smalley, *supra* note 117, § 4, at 99–100 (describing the elements of negligence as they relate to pharmacy errors). Therefore, the dispensing error will implicate all four facets of negligence whether or not reporting the error occurs. The reports only become important in determining the amount of damages that a jury is willing to award.

¹⁹³ However, by failing to make information concerned with improving safety confidential, error rates may not be as low as they could be because pharmacists may be reluctant to participate in an activity that exposes them to liability.

¹⁹⁴ See *INST. OF MED.*, *supra* note 7, at 109–10 (noting that the value of a confidential reporting system is that it creates less fear and encourages reporting because there is a smaller chance of the error being the subject of litigation).

essential to reduce the error rate.¹⁹⁵ Arguably, finding the self-evaluation privilege applicable to studies on errors would lead to increased patient safety and health by encouraging pharmacists to identify sources of mistakes, describing why errors occur, and generating ideas to reduce them.¹⁹⁶ However, two arguments rebut this assertion. First, opponents would argue that the privilege will be used to shield pharmacists and pharmacies from liability, ensuring that the injured party will not be fully compensated for an injury resulting from a negligent act. Also, by removing self-reports and other error-reduction methods from discovery, a means of holding pharmacists accountable would disappear.¹⁹⁷

2. Peer Review Privilege

Similar policy concerns to those of the self-critical analysis privilege exist when pharmacists consider another protection—the peer review privilege. While the self-critical analysis encompasses information discussed in peer reviews, its scope is much broader, including other areas in which a party has conducted a self-analysis, reporting or self-monitoring. The peer review privilege's scope is limited only to information discussed in peer reviews.¹⁹⁸ As with any common

¹⁹⁵ See Grasha & O'Neil, *supra* note 26, at 105–06 (explaining the value of self-monitoring is its ability to make pharmacists more aware of the factors that lead to errors, causing greater caution when similar factors are present in the future); *see also* Grasha, *supra* note 13, at 9, 10 (recommending that self-monitoring become part of the quality assurance process because research shows that self-monitoring can reduce errors by up to 21.7%).

¹⁹⁶ See Neville Moray, *Error Reduction as a Systems Problem*, in HUMAN ERROR IN MEDICINE, *supra* note 31, at 67, 83–85. This article argues that the legal system creates pressure to make rules that place blame on individuals. As a result, these rules “lead to inherently conservative behavior,” so that those bound by the rules choose “fail-safe” methods. However, the fail-safe path is not “necessarily best for the patient involved, but best in the sense that the person making the decision is safe from legal recourse.” *Id.* at 85. *But see* Kenneth DeVille & Carl Elliot, *To Err Is Human: American Culture, History, and Medical Error*, in MARGIN OF ERROR, *supra* note 2, at 25, 30–33 (explaining that new error reduction methods may also lead to new mistakes).

¹⁹⁷ See INST. OF MED., *supra* note 7, at 110 (reporting that many believe “[l]iability is part of the system of accountability and serves a legitimate role in holding people responsible for their actions”).

¹⁹⁸ Since this privilege is derived from the common law, it has not been adopted by every court. Legislation in some states codifies this privilege. However, if pharmacists were not in a jurisdiction that recognized this privilege either legislatively or by court mandate, information in the committee still might be protected depending on what was discussed. *See supra* notes 140–45 and accompanying text. Settlement discussions, for example, would still be protected. In federal jurisdictions, this protection comes from Federal Rule of Evidence 408, which specifically shields settlement discussions from discovery. If the proceeding occurred in the state courts, certain jurisdictions also protect settlement discussions. *See State ex rel. Malan v. Huesemann*, 942 S.W.2d 424, 426–28 (Mo. Ct. App. 1997) (observing that public policy favors settling disputes, making a pharmacists' settlement discussions with the State Board of

law privilege, it must overcome the presumption that “[p]rivileges are disfavored in the law and must be strictly construed,”¹⁹⁹ which means that courts are reluctant to grant the privilege.

Another drawback from the pharmacists’ perspective is that this privilege will not always be recognized. Two problems arise that also occur in the self-critical analysis privilege context. First, even if a state legislature were to create a peer review privilege,²⁰⁰ the “privilege [would] not [be] conclusive in an action brought in federal court under federal law.”²⁰¹ Also, a court will not grant blanket protection merely because the information is revealed in a peer review context. Instead, the court examines each assertion on a case-by-case basis, determining whether the public’s need for full disclosure outweighs the value of confidentiality.²⁰²

Since the peer review privilege may only exist subject to the preceding limitations, few courts have been willing to recognize this privilege. Some federal courts have gone so far as to say that “there is no peer review privilege under federal law.”²⁰³ Apparently, the only way that a federal court might recognize this privilege is if the court were exercising pendent jurisdiction and the state law creating a peer review privilege was “sufficiently compelling to be applied as federal common law.”²⁰⁴ In states where the legislature has not created a peer review privilege, state courts may recognize this common law privilege. In New Jersey, a state appellate court recognized the privilege because “the concerns are similar” to the self-critical analysis privilege, which the New Jersey Supreme Court had previously recognized.²⁰⁵ However, with such limited support among courts, it seems unlikely that pharmacists could rely on a court-created privilege

Pharmacy inadmissible because a danger existed that the jury would view these discussions as evidence of negligence).

¹⁹⁹ *Holland v. Muscatine Gen. Hosp.*, 971 F. Supp. 385, 389 (S.D. Iowa 1997).

²⁰⁰ See *supra* notes 140–45 and accompanying text.

²⁰¹ *Holland*, 971 F. Supp. at 388.

²⁰² *Id.* at 388–89.

²⁰³ *Sabatier v. Barnes*, No. CIV.A.99-2830, 2001 U.S. Dist. LEXIS 2240, at *5 (E.D. La. Feb. 21, 2001); see also *Tucker v. United States*, 143 F. Supp. 2d 619, 627 (S.D. W. Va. 2001) (refusing to recognize a federal review privilege because Congress addressed the scope of protection of medical review board hearings and failed to create a privilege).

²⁰⁴ *Id.*

²⁰⁵ *Bundy v. Sinopoli*, 580 A.2d 1101, 1106 (N.J. Super. Ct. Law Div. 1990). Although this court recognized the privilege, it was not prepared to grant blanket protection to the peer review documents. Instead, the court decided to undertake an *in camera* review of the materials. Once the court possessed these materials, it would balance the plaintiff’s particularized need for the peer review materials against the public’s interest in maintaining confidentiality. Thus, the privilege did not guarantee complete confidentiality because it merely prevented discovery of certain documents. *Id.* at 1106–07.

to protect peer review information. Instead, pharmacists would have to turn to the various state codes for protection.²⁰⁶

VII. ADMISSIBILITY INTO EVIDENCE

If a court were to find that a privilege did not exist under either Federal Rule of Evidence 501 or the analogous state statute that shields information from discovery, another rule of evidence may provide a means to garner some protection for self-critical analysis of errors and other remedial actions. Although the protection would not extend to discovery, it would make the information inadmissible in a court of law. This protection comes from Federal Rule of Evidence 407²⁰⁷ and its state analogues, which exclude evidence of subsequent remedial measures.²⁰⁸ Rule 407 protection means that a party accused of negligently injuring another would not have to reveal in court any corrective measures implemented following the harm.²⁰⁹ The rationale for this rule is twofold: (1) subsequent conduct should not necessarily be viewed as an admission of or proof of negligence; and (2) public policy favors improving safety, which this rule does by shielding remedial errors from the litigious courtroom environment.²¹⁰

For pharmacists, this rule of evidence would protect corrective steps taken after a patient's injury to ensure future safe drug dispensing practices. For example, if a pharmacist determined that an error stemmed from the fact that there were no double-check procedures in place,²¹¹ the implementation of systematic double-checking in the pharmacy would not normally be admissible in

²⁰⁶ See *supra* notes 140–46 and accompanying text (discussing state efforts at shielding peer review information from discovery).

²⁰⁷ Federal Rule of Evidence 407 states:

When, after an injury or harm allegedly caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is *not admissible to prove negligence*, culpable conduct, . . . or a need for a warning or instruction. This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment.

FED. R. EVID. 407 (emphasis added).

²⁰⁸ *Reichhold Chems., Inc. v. Textron, Inc.*, 157 F.R.D. 522, 524 (N.D. Fla. 1994).

²⁰⁹ See FED. R. EVID. 407 committee note to the 1997 Amendment (stating that additional language was inserted to clarify that actions taken prior to an injury are not shielded by the rule, making only subsequent activity inadmissible as evidence).

²¹⁰ FED. R. EVID. 407 advisory committee's note on proposed rules.

²¹¹ Double checks are the systematic checking of prescriptions by an individual who did not fill the prescription to ensure that the prescription is dispensed as prescribed. See *Maybe Santa's on to Something*, *supra* note 13.

court under Federal Rule of Evidence 407. The new double-checking procedure would be viewed as attempting to remedy a past error.

An argument could be made that critical self-analyses also would fall under the framework of this Rule.²¹² If counsel were to contend that a pharmacist performed self-analysis to become a safer and better pharmacist after every incident of an error, this subsequent step of self-analysis might be considered remedial.²¹³ However, it is not certain that monitoring or reporting of earlier errors would be protected because they would not be remedial for a specific error event. While self-critical analyses may not be protected, it is certain that more immediate actions taken to create a safer pharmacy environment after a patient's injury would be inadmissible because of their remedial nature.²¹⁴ For instance, re-organizing the pharmacy environment, instituting double checks, and refining dispensing procedures in response to errors would be considered remedial measures and therefore excluded from evidence to prove negligence.

However, Rule 407 would not provide blanket protection. Since this is a rule of evidence, exceptions exist. Evidence of remedial measures can be introduced if an injured patient uses them "for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment."²¹⁵ Therefore, whatever protection this rule afforded the double

²¹² See *Reichhold Chems.*, 157 F.R.D. at 524 (arguing that the self-critical analysis privilege essentially follows the policy arguments for Rule 407).

²¹³ The Rule defines remedial steps as "measures [being] taken that, if taken previously, would have made the injury or harm less likely to occur." FED. R. EVID. 407.

²¹⁴ See *supra* note 73 and accompanying text (describing changes that can be made to the physical environment of a pharmacy).

²¹⁵ FED. R. EVID. 407. While the evidence of the remedial measure will enter the proceedings to prove some other purpose, the plaintiff cannot use such evidence to imply or infer that the corrective steps were an admission of negligence. See *Hagaman v. Merrell Dow Pharm., Inc.*, No. CIV.A.84-2202-S, 1987 U.S. Dist. LEXIS 6124, at *29 (D. Kan. June 26, 1987) (stating that a remedial measure could have been undertaken for "any number of reasons," therefore to allow their introduction "would violate the spirit if not the letter of Federal Rule of Evidence 407"). Even if the jury were to make this determination independently, the attorney who objected to this evidence could request a limiting instruction from the judge to warn the jury that this evidence was not being offered to prove negligence. See FED. R. EVID. 105; *Hardy v. Chemetron Corp.*, 870 F.2d 1007, 1014 n.1 (5th Cir. 1989). Also, even if these remedial measures were entered into evidence for some other purpose like impeaching a witness, the attorney could always object to its introduction under Federal Rule of Evidence 403 as creating "unfair prejudice, confusion of the issues, . . . and waste of time." See FED. R. EVID. 407 advisory committee's note. Rule 403 states that:

Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.

check example of the previous paragraph might not apply if the injured used this double check as evidence of something other than negligence, such as to rebut a claim that these double checks were not feasible.²¹⁶ However, if such evidence were to enter, counsel for the pharmacy could reduce the danger of this evidence being used to infer pharmacist negligence by requesting a limiting instruction.²¹⁷ Also, counsel for a pharmacist can prepare the pharmacist when taking the stand to avoid answering questions in such a way as to allow for the remedial measure evidence to enter the court proceedings.²¹⁸

However, this possible admissibility of remedial measures under Federal Rule 407 (and its state law counterparts) will not comfort all pharmacists for two reasons, even if admissibility of such measures is not supposed to create an inference of negligence. First, the lack of a total bar against admissibility might discourage pharmacists from implementing error-reducing techniques. While the occurrence of an error is discouraging, pharmacists do not want to have their good intentions (expressed by safer dispensing procedures) to become evidence used against them in a lawsuit. Second, since this rule only protects subsequent remedial measures, other methods of reducing errors (and thus improving patient safety) would not be protected under Rule 407. Peer review, pharmacy error research, risk management incident reports, and other methods of error reduction do not appear to fall within the parameters of the rule since they do not involve

FED. R. EVID. 403. Thus, if an attorney were to argue successfully that, even though this evidence of a remedial measure was used to impeach a witness, it would have minimal probative value when compared with the unfair prejudice that would result by revealing the corrective steps, the information would still be excluded from evidence.

²¹⁶ If a pharmacy representative were to claim that double checks were too difficult or time consuming to implement in the pharmacy, opposing counsel could then introduce evidence that such procedures were implemented to impeach the testimony.

²¹⁷ See FED. R. EVID. 105 (stating that “[w]hen evidence . . . is admissible . . . for one purpose but not admissible . . . for another purpose . . . , the court, upon request, shall restrict the evidence to its proper scope and instruct the jury accordingly.”); *Hardy*, 870 F.2d at 1014 n.1 (stating that evidence of remedial measures used to impeach a witness “will be accompanied by a limiting instruction cautioning the jury to consider the evidence only as it bears upon the credibility of the witness or witnesses”). Some fear that the exceptions to Rule 407 will “swallow up” the rule; however, courts will apply the exceptions only when: (1) a party elicits impeachable statements from witnesses and then uses Rule 407 to protect the statements; and (2) a danger exists that allowing the impeachable statements to go uncontested will have deleterious effects. Also, there is no reason to fear the exceptions because the admission of this evidence will not “create a foregone conclusion that plaintiffs will always prevail” because this evidence will have to be weighed with the totality of the evidence. *Id.*

²¹⁸ For example, if a pharmacist were to deny the feasibility of implementing an error reduction measure during witness testimony, such a denial would place the issue in controversy, allowing for evidence of the remedial measure to be admitted. Although the remedial evidence could not be used to suggest negligence under Federal Rule of Evidence 407, its admission potentially might influence the jury to believe that the failure to implement a remedial measure was a sign of negligence.

measures that “if taken previously, would have made the injury or harm less likely to occur.”²¹⁹ Therefore, Rule 407 provides protection for only a limited set of pharmacist activities. Yet, the Rule is another source of protection, one additional component to this complex and disparate collection of legal protections on which pharmacists may rely to ensure that the jury does not hear evidence of past errors.

VIII. ANOTHER PERSPECTIVE ON THIS COMPLEX SORROW

Presently a patchwork of protection exists for pharmacists to try to shield what they consider to be confidential information. While pharmacists want a statute or statutes to shield from discovery or admissibility every piece of information and every process that might lead to a reduction in pharmacy errors, this solution is unlikely for two reasons. First, the opposing side—the injured patient—would challenge attempts to draft legislation granting blanket protection. In some instances, it might be unfair to deny an injured patient access to information that could prove negligence.²²⁰ Second, legislation will never include every situation or scenario that arises—there will always be gaps in the legislation.²²¹ Therefore, instead of delaying activities aimed at reducing dispensing errors while waiting for a legislature to enact the perfect piece of legislation, pharmacists should embrace and implement the measures that have been shown to improve patient safety.

The most certain means of reducing liability is through detecting error and lowering the number of errors by implementing safety mechanisms,²²² like altering the pharmacy work environment and utilizing such error identification

²¹⁹ FED. R. EVID. 407.

²²⁰ *ASHP Government Affairs: Legislative Issues Summary*, *supra* note 138 (reporting that Senate bills trying to establish a national voluntary reporting system for medical errors were stymied because of disagreement over the type of legal protections for providers who submit information).

²²¹ For instance, if a statute protects peer review information, the scope of protection does not extend to self-monitoring or reporting systems. *See supra* note 143 and accompanying text.

²²² *But see* DeVille & Elliot, *supra* note 196, at 30–33. This article emphasizes the dual role of innovation—while its goal is to prevent mistakes, it can “also represent a new source of potential error.” *Id.* at 32. Therefore, implementing improvements may in the end lead to other types of medical error. For example, the treatment of compound fractures in the early 1800s meant amputation or death, but with advances in medicine, preserving the limb became feasible. Subsequently, any complications that resulted from setting the fracture, such as deformity or frozen joints, were viewed as an error, even though death or amputation had previously been accepted. While this advance improved patient health, it also created problems for doctors as complications from setting fractures became the most common subject of medical malpractice suits in the early 1900s. *Id.* at 30–33.

processes as peer review, self-monitoring, and reporting errors.²²³ A reorientation of perspective is necessary. Instead of seeing these safety-enhancing procedures as a way to increase liability, pharmacists should view these procedures as a means of reducing liability and improving the health and safety of pharmacists. A suit can be filed any time a dispensing error occurs,²²⁴ and no magical legal principle exists to keep suits from being filed. Privileges and immunities cannot halt the filing of a suit—they merely protect certain types of information from being revealed to the opposing party, making it more difficult to prove negligence. However, the only certain way to avoid negligence is to stay out of court, not to have favorable discovery, privilege, and evidence laws. If pharmacists commit fewer errors by implementing these error-reduction methods and procedures, they will injure fewer patients, and consequently they will be exposed to fewer lawsuits.

When pharmacists and pharmacies are confronted with lawsuits, the present legal system provides protection when plaintiffs go beyond the scope of what is necessary to prove negligence. Pharmacist may counteract an injured patient's overreaching in the discovery phase or at trial through two interrelated ways: by using explicit rules and laws provided by federal and state courts and legislatures; and by grounding their arguments for the use of these rules in recognized public policy.

During the discovery phase of litigation, the Federal Rules of Civil Procedure require that the information requested in discovery be relevant to the case at hand.²²⁵ However, not all relevant information needs to be open to discovery because privileges from discovery and court protective orders exist to shield information from the opposing party.²²⁶ At trial, rules of evidence will deny the admission of certain forms of self-critical information, based on policies that encourage safety improvements.²²⁷

Policies become prominent when a court decides whether to grant a privilege or protective order. Thus, the privileges available to pharmacists demand that the court balance competing policies—the right to access against the rights to confidentiality and improving safety. Where promoting the public's health and maintaining confidential information outweigh the policy of giving the public

²²³ See Elizabeth Allan Flynn & Kenneth N. Barker, *Medication Errors Research*, in MEDICATION ERRORS, *supra* note 16, at 6.1, 6.10–6.14 (listing anonymous self-reporting, incident reports, in-depth analysis of errors, and self-report and observation as examples of methods to detect errors); see also *supra* notes 47–56, 58–70, 76–78 and accompanying text.

²²⁴ See ANNAS, *supra* note 30, at 4 (observing that the answer to the question of whether one can be sued is “always yes . . . since in the United States anyone can sue anyone for almost anything”).

²²⁵ FED. R. CIV. P. 26(b)(1).

²²⁶ Vandegrift, *supra* note 125, at 188–89 (suggesting that an alternative to the self-critical analysis privilege is a protective order).

²²⁷ *Id.* at 189–90; see also *supra* notes 207–19 and accompanying text.

access “to every man’s evidence,”²²⁸ pharmacists will have satisfied one of the requirements for obtaining protection. Thus, pharmacists who have participated in an error identification process like self-evaluation, peer review, or reporting may use policy arguments either to repel production of the material in discovery or to deny the admissibility of the evidence in court when litigants seek to expose this information.

Courts cite four policies when discussing whether a privilege should exist or why a certain court action should be taken. First, courts are interested in ensuring the safety of the patients.²²⁹ Second, courts want to encourage safety improvements.²³⁰ The third and fourth policies are interrelated—to encourage participation in systems and procedures aimed at reducing errors²³¹ and to create confidential processes.²³² When pharmacists adopt methods to ensure patient safety and reduce dispensing errors, they can construct strong policy arguments in favor of maintaining the confidentiality of this information. Although the argument will not always sway a court because strong policies exist in the patient’s favor,²³³ pharmacists’ arguments will not be easily discarded, especially if they defend themselves in jurisdictions that explicitly recognize a peer review privilege or a self-critical analysis privilege.²³⁴

Before a suit is even filed, pharmacists have legal and systematic safeguards that also may provide protection. A *prima facie* case of negligence requires proof

²²⁸ *Univ. of Pa. v. EEOC*, 493 U.S. 182, 189 (1990) (quoting *United States v. Bryan*, 339 U.S. 323, 331 (1950)).

²²⁹ See *McClure v. Walgreen Co.*, 613 N.W.2d 225, 231 (Iowa 2000) (implying that patient safety is an important policy when the court found a pharmacy’s “conduct particularly egregious” for not warning the patient of dangerous side effects of a drug).

²³⁰ See *Brem v. DeCarlo*, 162 F.R.D. 94, 102 (D. Md. 1995) (finding a strong public interest in promoting quality health care); FED. R. EVID. 407 advisory committee’s note (explaining that the purpose of the rule is to promote the advancement of safety).

²³¹ See *Bredice v. Doctors Hosp., Inc.*, 50 F.R.D. 249, 250 (D.D.C. 1970) (finding a privilege of self-critical analysis to exist because the protection of information would improve medical procedures).

²³² See *id.* (observing that “[c]onfidentiality is essential to effective functioning” of peer review and that without this confidentiality there would be no “[c]andid and conscientious evaluation”).

²³³ Public policy in the patient’s favor includes: (1) open access to relevant information; see *Tucker v. United States*, 143 F. Supp. 2d 619, 626 (S.D. W. Va. 2001); and (2) holding those negligent accountable for their actions. See *Fed. Ins. Co. v. Honeywell, Inc.*, 641 F. Supp. 1560, 1563 (S.D.N.Y. 1986) (noting that there is a “strong, indeed intractable, public policy that favors making parties accountable for gross negligence”); *Beach v. City of Phoenix*, 667 P.2d 1316, 1320 (Ariz. 1983) (observing that there is a “well-established public policy of holding governmental bodies accountable for their negligence”).

²³⁴ See *Bundy v. Sinopoli*, 580 A.2d 1101, 1105 (N.J. Super. Ct. Law Div. 1990) (stating that the New Jersey Supreme Court has recognized the “concept of self-critical analysis as applied to the health care area”).

that: (1) the pharmacist owed a duty to the injured patient; (2) the pharmacist breached the duty; (3) an injury occurred; and (4) the breach caused injury.²³⁵ If one of these elements is absent, a patient will not have a winning case against the pharmacist,²³⁶ which should discourage frivolous suits.²³⁷

Also, methods of creating confidential systems exist that do not require the law to guarantee confidentiality.²³⁸ For instance, some reporting systems do not require the name or location of a pharmacy when a pharmacist submits information about errors.²³⁹ Also, researchers may gather information about pharmacy errors without knowing who committed the error.²⁴⁰ If the researchers who gather this information have no records on a pharmacist's identity, an injured patient has no incentive to subpoena or force disclosure of these records. This would merely be a waste of resources and time to try because the results would be fruitless. Therefore, legal and extralegal measures exist that potentially protect pharmacists from liability.

While not all these methods ensure absolute protection from liability, their existence serves as a potential shield. The focus on some yet-to-be-implemented legal protection distracts pharmacists from another method available to reduce liability—implementing known procedures for limiting errors. Instead of calculating whether each new method to reduce errors will increase liability, pharmacists should realize that utilizing these techniques will reduce errors. It is this lower error rate, not an ideal piece of legislation, that will diminish the chance of liability, since fewer pharmacy errors means fewer injuries, reducing the

²³⁵ Smalley, *supra* note 117, § 4, at 100.

²³⁶ See *Huggins v. Longs Drug Stores Cal., Inc.*, 862 P.2d 148, 154 (Cal. 1993) (finding no duty to exist between a pharmacist and the parents of an infant whom the pharmacist injured).

²³⁷ Besides the prospect of spending money on a losing claim, a plaintiff is also in danger of having a court impose sanctions for frivolous suits. See FED. R. CIV. P. 11 (authorizing a court to grant sanctions for frivolous claims, harassment, undue delay, or insufficient evidentiary proof).

²³⁸ See Smetzer et al., *supra* note 57, at 19.12 (listing a number of ways for error reports to be shielded from discovery that do not rely on common law privileges or statutes including: (1) separating the error report from the patient's record; (2) prohibiting photocopies of reports; (3) neglecting to mention the error in a patient's record; (4) including only the facts in an error report, not opinions, conclusions, admissions, or accusations; (5) defining the purpose and proper use of an event report in terms of policies and procedures; and (6) including a guarantee of confidentiality with every form); see also INST. OF MED., *supra* note 7, at 124–27 (describing the following three ways to guarantee confidentiality through non-legal means: (1) promising and practicing confidentiality; (2) anonymity in reporting; and (3) de-identification (the process of removing names from a reporting system's database)).

²³⁹ INST. OF MED., *supra* note 7, at 125–26.

²⁴⁰ Grasha, *supra* note 13, at 7 (designing a system of analyzing errors “under conditions of anonymity and confidentiality” by having pharmacists record errors in booklets and then having them return them anonymously by mail).

number of opportunities to sue for these mistakes. Therefore, pharmacists should recognize that tools at their disposal may decrease their chances of being held liable. By waiting for the courts or the legislature to take the perfect step, pharmacists seem to expose patients to the risk of dispensing errors, ensuring liability when these risks become reality.

IX. CONCLUDING THE COMPLEX SORROW

While the law is not friendly to the development of new techniques to reduce pharmacy errors, it is not an antagonist either. Three potential sources exist to shield this information—the common law, congressional legislation, and state law. However, if a suit is filed, pharmacist's counsel cannot passively point to a statute or privilege that grants immunity. Instead, counsel must actively employ policies, invoke various rules of procedure or evidence, and advocate the reasons for the application of a statute. In effect, a judge must be convinced that the attempts to reduce errors are worthy of some form of protection from the litigation process. The success of these arguments varies extensively from jurisdiction to jurisdiction and judge to judge.

This potential for protection is not reassuring to pharmacists because they want absolute certainty that the information will remain confidential and shielded from court processes. Pharmacists' sorrow is complex because it encompasses a contradiction—desiring to maintain the status quo out of a fear of liability while at the same time desiring changes to reduce errors and improve patient safety. Without these assurances of protection from liability, pharmacists often claim that the risk is too great for them to use certain error-reduction methods because these methods increase the chances of a jury finding liability.

Instead of focusing on this heightened potential for liability that might emerge from various error-reduction methods, it may be beneficial to reorient thinking away from a perspective that views reporting, self-monitoring, or peer review as enhancing one's exposure to liability toward a view that considers these techniques for their potential in increasing patient safety. Negligence may only arise when there has been a pharmacy error. Therefore, these processes have value, as potential sources to reduce, not enhance, liability by decreasing the number of errors. While the methods of error reduction might leave a trail of evidentiary mistakes and errors, potentially exposing some pharmacists to liability for having strayed from the standard of care of a reasonable pharmacist, this is not their goal and arguably not the inevitable result. Once pharmacists reduce the frequency of errors, they should be liable in far fewer situations since the error-reduction methods are designed to minimize and eliminate errors.

Any time a dispensing error occurs a tension between the pharmacist and patient arises. Emotions, injury, and abstract principles of law will interact in complex ways. It will never be possible to unravel this complexity, but there is one certain way to avoid it—eliminating or reducing pharmacy error. In the law,

there are no solutions for reducing pharmacy-dispensing errors. The law merely creates incentives to eliminate error, either by holding people accountable for negligent actions or by ensuring the confidentiality of pharmacy-error information. Therefore, the law only indirectly serves as a means to avoid the complexity of dispensing error. The only certain way to avoid or reduce the number of encounters patients and pharmacists have with this complex sorrow is to develop and utilize methods that are proven to reduce errors.